Bayer

CLINITEK® 500
Urine Chemistry Analyzer

SERVICE
MANUAL

Model 6470

**Revised
December 1999**

Section Description	Section number

Section Description   Section number

CHAPTER ONE - GENERAL DESCRIPTION   *Return*

1-0   Introduction

The CLINITEK® 500 Urine Chemistry Analyzer is capable of processing in excess of 500-urine chemistry reagent test strips per hour. It was developed as the next generation replacement system for Bayer's CLINITEK® 200+ Urine Chemistry Analyzer and differs primarily from this system in its higher throughput (*over 500 tests per hour*), non-pacing operation and enhanced touch-screen based user interface.   In addition to direct support for a wide range of MULTISTIX® Reagent Strips, the Clinitek 500 instrument can make and report a qualitative determination of urine color.

1-1   Features

The major improvement over previous systems has been in workflow reduction. Customers can reduce their technician time spent on processing urine samples. To achieve this overall benefit, the following features were implemented:

- Touch screen display for easier and faster operation,

- Non-pacing operation mode to process samples at the users pace,

- Increased throughput for completing work faster,

- Automatic urine color determination to speed up data entry,

- Confirmatory Sieve with Batch Results Editing to eliminate time consuming mainframe editing,

- Memory Recall which allows customers to display the test results from specific samples,

- Interactive Bar Code Reader Support (optional) to enter patient ID and color and clarity more efficiently,

- Internal Automatic Calibration to improve reliability of results.

- No warm-up time for starting a batch.

- User Interface available in English, German, French , Italian, Spanish and Kanji with applicable help screens The general description of the CLINITEK® 500 Urine Chemistry Analyzer can be found on pages 1.0 to 1.5 in the Operating Manual.

1-2   General Specifications

Size:
  Depth-32.4 cm (12.8 in.)
  Width-37.7 cm (14.8 in.)
  Height-28.2 cm (11.1 in.)

Weight:
  7.4 Kg (16.3 lb)

Input voltage:
Auto Ranging 90 VAC to 264 VAC
50 – 60 Hz

Maximum Power Input-
  72VA

Thermal output:
  246 BTU/hr

Line Leakage Current:
< 0.5 milliamperes in normal condition
< 3.5 milliamperes in single fault condition

(Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL 3101-1, CSA 22.2 No. 1010.1 and IEC 1010-1)

Ambient Operating Temperature Range:
  18°C to 30°C (64°F to 86°F

Ambient Operating Humidity Range:
  20% to 85% relative humidity

Optimum Operating Conditions:
  22°C to 26°C (72°F to 86°F)
35% to 55% relative humidity

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Chapter Two - Methods Overview   *Return*

2-0   Introduction

The CLINITEK 500 Urine Chemistry Analyer
is a scanning reflectance photometer, which
reads the change in color on Bayer Multistix®
Reagent Strips. Please refer to the product
insert that comes with the specific Multistx®
Reagent Strips being used for a description
of the its methods.

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CHAPTER THREE – INSTALLATION   *Return*

3-0   Introduction

Refer to the installation section of the
Operating Manual.

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CHAPTER FOUR – OPERATIONS / PROCEDURES   *Return*

4-0   Introduction

Refer to sections 3 and 4 of the Operating
Manual for instructions on the operation of
the CLINITEK®500 Urine Chemistry
Analyzer.

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CHAPTER FIVE - PREVENTIVE MAINTENANCE *Return*

5-0   Introduction

This section describes cleaning and preventative maintenance test procedures that should be performed as a matter of routine anytime that a CLINITEK 500 instrument is in Bayer Diagnostics possession. Following these procedures will help identify possible system weaknesses prior to them manifesting themselves as field failures.

5-1   Cleaning

Reference
CLINITEK 500 Operating Manual, Section 5 "CARE OF THE INSTRUMENT" for cleaning instructions.

5-2   Lubrication

Push Bar Slide Arm Shaft

1. Clean the Push Bar Slide Arm Shaft with alcohol.

2. Apply a thin coat of Lubriplate 630-AA Multi-purpose Grease, part number 50336008.

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CHAPTER SIX – FUNCTIONAL DIAGRAMS / THEORY   *Return*

6-0   Introduction

The CLINITEK 500 Instrument is a stand-alone, semi-automatic urine chemistry analyzer. The instrument is a scanning reflectance photometer capable of outputting clinically significant diagnostic results when used with a variety of Bayer reagent strips.

Primary features of the system include the ability to automatically detect the presence of a Bayer reagent test strip which has been presented for processing, a throughput in excess of 500 reagent tests per hour and an advanced touch-screen based user interface which gives the customer considerable control over the operation of the system.

The instrument has several functional sub-systems: Reagent Transport, Readhead system, Data processing and User interface. Within each of these sub-systems there are specific electrical, mechanical and software components. The overall operation of the instrument is controlled by two independent processors, the first managing data I/O and the user interface. The second controlling basic instrument hardware functions.

6-1   General Operation

The general operation of the instrument is as follows:

1. (Refer to figure 6-1)

2. The user dips a Bayer urine test strip into a urine sample and places it onto the load zone of the CLINITEK 500 instrument's Fixed Table.

3. A strip detector senses the presence of a reagent strip on the Fixed Table.

4. Detection of a reagent strip activates the Push bar that pushes the reagent strip to the right side of the load zone on the Fixed Table.

5. When the Push bar reaches the far right end of its travel, the strip detector verifies the presence of a reagent strip. If a strip is present, the test sequence number is incremented and the Moving Table is activated to move the reagent strip into the Readhead area in preparation for analysis. (This area is encased under a permanent hood to prevent ambient light from interfering with the system's reflectance measurements.)

6. The Moving Table continues to be activated every 7 seconds and advances the strip to the right each time by approximately .45 inches (1.143 cm).   top of chapter

7. The Moving Table advancement places a strip under either Readhead (at approximately 25 or 67 seconds after dipping),if a strip is under either readhead then the Readhead will scan the strip taking measurements in the Red, Blue, Green and IR wavelengths.

8. After a Strip has been read under both readheads the data will be analyzed and the results passed to processor "1" for output to devices based upon system configuration options selected by the user.   top of chapter

Instrument Operation Overview Block Diagram

```
                              ┌─────────────┐◄──────────────────────────────┐
                              │    Ready    │                               │
                              └─────────────┘                               │
                                     │                                      │
                                     ▼                                      │
                              ┌─────────────────┐      NO                   │
                              │ Strip placed on │──────────►────┐           │
                              │   load zone     │               │           │
                              └─────────────────┘               │           │
                                     │ YES                       │           │
                                     ▼                           │           │
                              ┌──────────────────────┐           │           │
                              │ Push Bar moves strip  │           │           │
                              │ to verification       │           │           │
                              │ position              │           │           │
                              └──────────────────────┘           │           │
                                     │                           ▼           │
               yes                   ▼                    ┌──────────────┐    │
           ◄─────────────── ┌──────────────────────┐     │ Push Bar     │    │
           │                │ Strip present at      │     │ returns to   │    │
           │                │ right side detector   │     │ left position│    │
           │                └──────────────────────┘     └──────────────┘    │
           │                       │ NO                         ▲             │
           │                       ▼                            │             │
    ┌──────────────┐      ┌──────────────────────┐              │             │
    │ Push Bar     │      │ Pusher moves strip    │              │             │
    │ moves strip  │      │ to Moving table       │              │             │
    │ to the       │      │ pick-up and stays     │              │             │
    │ moving table │      │ at far right position │              │             │
    │ pick up      │      └──────────────────────┘              │             │
    └──────────────┘             │                              │             │
           │                     ▼                              │             │
           │            ┌──────────────────────┐                │             │
           │            │ Moving table advances │                │             │
           │            │ 3 positions           │                │             │
           │            │ (3 instrument cycles, │                │             │
           │            │  21 seconds)          │                │             │
    ┌──────────────┐    └──────────────────────┘                │             │
    │ Push Bar     │             │                              │             │
    │ returns to   │             ▼                    NO         │             │
    │ the far left │   ┌──────────────────────┐──────────►──────┘             │
    │ and waits for│   │ Readhead 1 detects    │                              │
    │ next strip   │   │ strip present         │                              │
    └──────────────┘   └──────────────────────┘                              │
           │                  │ YES                                           │
           │                  ▼                                               │
           │           ┌──────────────────────┐                              │
           │           │ Push Bar returns to   │                              │
           │           │ left position         │                              │
           │           └──────────────────────┘                              │
           ▼                  │                                               │
    ┌──────────────┐          ▼                          NO                   │
    │ Moving table │──────►┌──────────────────────┐──────────►───────┐        │
    │ advances     │       │ Strip at either       │                 │        │
    │ strip every  │       │ readhead              │                 │        │
    │ 7 seconds    │       └──────────────────────┘                 │        │
    └──────────────┘          │ YES                                 │        │
       ▲                      ▼                                     │        │
       │              ┌──────────────────────┐                     │        │
       │              │ Initialize readhead   │                     │        │
       │              │ position              │                     │        │
       │              └──────────────────────┘                     │        │
       │                      │                                     │        │
       │                      ▼                                     │        │
       │              ┌──────────────────────┐                     │        │
       │              │ Calibrate             │                     │        │
       │              └──────────────────────┘                     │        │
       │                      │                                     │        │
       │                      ▼                                     │        │
       │              ┌──────────────────────┐                     │        │
       │              │ Read strip(s)         │                     │        │
       │              └──────────────────────┘                     │        │
       │                      │                                     │        │
       │                      ▼                                     │        │
       │              ┌──────────────────────┐                     │        │
       │              │ Select readings       │                     │        │
       │              └──────────────────────┘                     │        │
       │                      │                                     │        │
       │                      ▼                                     │        │
       │              ┌──────────────────────┐                     │        │
       │              │ Calculate reflectances│                     │        │
       │              └──────────────────────┘                     │        │
       │       NO             │                                     │        │
       ◄──────────── ┌──────────────────────┐◄───────────────────┘        │
                     │ Have 12 moving table  │                            │
                     │ cycles occurred       │                            │
                     │ without detecting a   │                            │
                     │ strip under readhead 1│                            │
                     └──────────────────────┘                            │
                            │ yes                                         │
                            ▼                                            │
                            └────────────────────────────────────────────┘
```
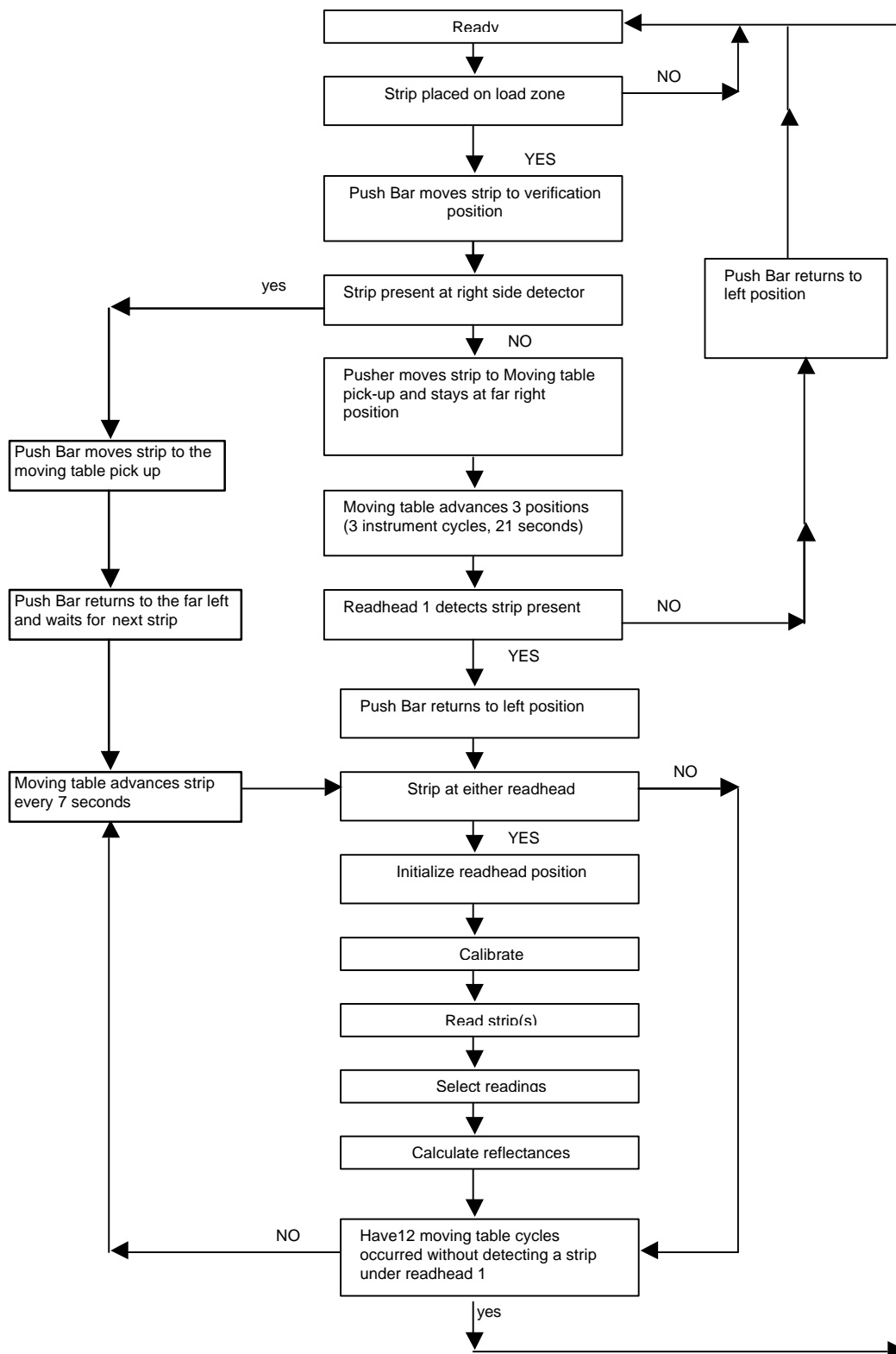
Figure 6-1

6-2   User Interface

The user interface consists of: a touch screen display, audible and visual alarms, internal and external printer options, a serial RS232 input for bar-coded sample ID, a second RS232, data port for interface with an external customers information system (computer) and a third RS232 serial port for future customer options. All user interface functions are controlled by processor #1.   top of chapter
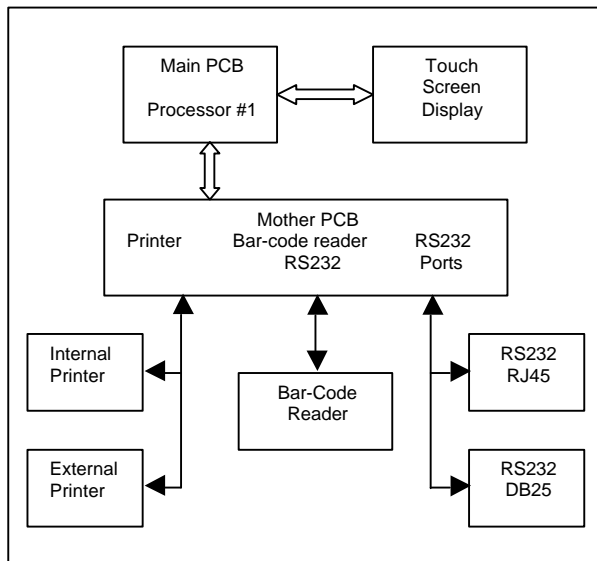

Figure 6-2

6-3   Power Distribution

The AC line input for the instrument first passes through the power entry module. This module is a combination of an on/off switch and line cord receptacle. Note that the AC line fusing for this product is located inside of the power supply module and is not considered a serviceable item.

The power supply is a switching power supply. The AC input voltage is automatically compensated for and has a range of 90-264 VAC, 50-60 Hz. The outputs of this supply are +5 VDC and +12 VDC, -12 VDC and -5 VDC. The exact voltage level of the +5 VDC output can be adjustable by use of potentiometer V1 adjacent to terminal block TB2 (refer to figure 8-1). The power supply is protected from overload by use of fold-back current protection and an internal fuse. An internal over-temperature protection circuit with automatic reset provides additional protection. Output noise and ripple will be less than .3% RMS (noise) and 1% peak-to-peak (ripple) for the main +5 VDC output.

Power is distributed throughout the instrument via the MOTHER PCB. A cable connects the power supply to connector P12 of the MOTHER PCB. Connector P12 is a six pin connector and has the following pin out: Pins 2 and 3 of this connector are the DC ground, pin 1 is -12 VDC, pins 4 and 5 +5 VDC and pin 6 +12 VDC.

There are two auto reset fuses F1 and F2 which are soldered into the MOTHER PCB and provide current protection for the external Bar code reader. Fuse F1 is for the +5 VDC and fuse F2 is for +12 VDC

Power to the internal printer is supplied via connector P7 on the MOTHER PCB, Pins 1 and 2 are +5 VDC, Pin 3 is DC Ground.

The strip detector circuit operates off both +12 VDC and –12 VDC. This power is supplied through connector P8 of the MOTHER PCB. Pins 1,4 and 5 are GND while pin 3 is +12 VDC and pin 2 is –12 VDC.   top of chapter

6-4   Mother PCB

The MOTHER PCB serves primarily as an interconnection board for many of the system's I/O functions and contains a portion of the instrument's control circuitry. Each of the functions performed by the MOTHER PCB is described below.

6-4-1 Motor Drive Circuits

The drive circuits for the moving table, Push bar and readhead all utilize the same circuit design. U5, U6 and U7 are motor controller IC's which convert the instructions from Processor #2 (connector J2) to drive signals for the stepper motors. The input signals are Step (pin 11), OE (pin 15), and Direction (pin 14). The half step control line is tied high to the +5 VDC thus disabling this function on all IC's. U6 also has pin 11 tied to the +5 VDC which fixes the motor direction to clockwise rotation.

The output of the motor controller IC drives a four phase stepper motor. The outputs are: pin 8 (A output), pin 1 (B output), pin 6 (C output) and pin 3 (D output). Each of the outputs is clamped to ground through a reversed bias schottky diodes (D1-D12).

The stepper motors are four phase and have typical coil resistances as follow:

> Readhead motor 24 ohms
> Push Bar motor 53 ohms
> Moving Table motor 32 ohms

6-4-2 Optical Sensors

There are three optical sensors that are used to confirm the following:

1. Fixed Table is in place (PN 40453222)

2. Push Bar interrupt sensor (PN 40453233)

3. Moving Table interrupt sensor (PN 40453221)

All of the sensor outputs are routed to the Main PCB through connector J1

The Fixed Table in place optical sensor is located on the left support of the fixed table guide and is used to determine if the fixed table is fully seated. The sensor plugs into connector P10 on the Mother PCB. If the signal is not present it will result in a general system error "26" and will halt operation.

The Push bar interrupter is used to determine if the push bar has cycled completely. The sensor plugs into connector P9 on the MOTHER PCB. If the signal is not present it will result in a general system error "24" and will halt operation.

The Moving Table interrupter is used to determine if the strip transport is working properly. Once the system initiates a test cycle and activates those mechanisms used to advance a regent test strip, it expects to see a signal change from this sensor within a certain time window. This sensor plugs into connector P1 on the MOTHER PCB. If a signal is not seen, the system interprets this as a problem with the moving table and reports a general error "23" which will halt operation.

6-4-3 Printer interface

The external printer port J3 is located on the Mother PCB. In addition to providing the routing from Main PCB connector J1, to connector J3 mounted to the rear of the instrument, the data lines are clamped for noise suppression with diodes D14 through D24.

6-4-4 Serial Ports

The Mother PCB also provides interconnection from the Main PCB (connector J2) to the three RS232 serial ports J5, J6 and P4. Connector J6 is a RJ45 8 pin modular jack and connector P4 is a 25 pin female D-Connector. These are for serial communication with external equipment.

The remaining port J5 is an 8 pin RJ45 connector that is dedicated for use with a bar code reader. On this jack, pins 1 & 3 are tied to ground, pin 4 is serial output from the Main PCB, pin 5 is serial input. Pin 6 provides +5 VDC output and pin 7 provides a +12 VDC output for the reader.

6-4-5 Moving table

Following confirmation of reagent strip presence by the strip detector, movement of the reagent test strip is then performed by the moving table assembly. This assembly is driven by a stepper motor which is under the direct control of Processor 2 (Refer to figure 6-3).
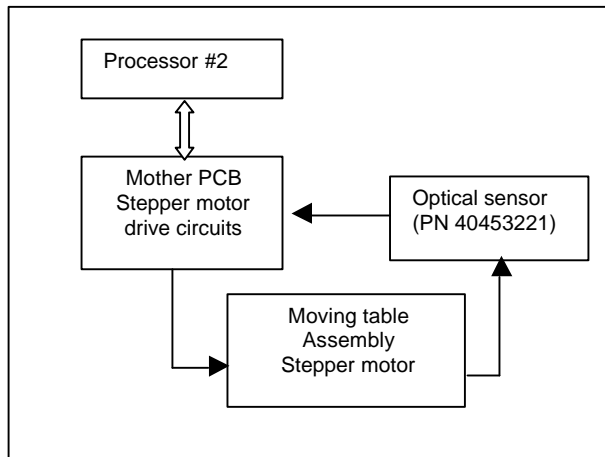
Figure 6-3

Processor #2 sends control signals for direction and a pulse train to the stepper motor controller chip on the mother PCB. The controller converts the pulse train into four outputs; phase A, phase B, phase C, phase D, for the windings of the stepper motor. An optical interrupter detector is used to establish a home location for the moving table and provides a means of timing its operation to detect errors in its motion.   (Refer to section 6-4-1 for more details on the motor drive circuits)

6-5   Main PCB

The Main PCB contains the instrument's two Processors and all of their associated support circuitry. Processor #1 (U21) is an 80C517A (8051 family) which is a surface mount IC. Processor #2 (U1) is a Dallas DS2253T and is mounted as a SIMM in a socket. The system utilizes the Processors as follows:

Processor #1 is used for serial communications, bar code communications, internal and external printer functions, converting decode values to clinical levels, and provides all user interface functions. It communicates with Processor #2 and includes the ability to program Processor #2.

Processor #2 is used to control strip movement (strip detector, push bar motor, moving table motor), readhead movement, perform error checking, read the strip, perform calculations on strip data, store one set of results (reflectance, decodes and color) and maintain real time and date.

The PCMCIA card is used to store the CT 500 software and to retain the user configuration settings.

IC U24 is the system RAM (128K) that is used to store patient results.

IC's U13 &U14 are quad comparators used in conjunction with DAC U29 and processor 2 for the strip detector control.

Data for the internal printer is sent to latch U17 where it is output through an octal ferrite to the printer on connector J3.

Data for the external printer is sent to U19, a buffer, where in conjunction with a response to a strobe signal it is sent out connector P1.

The Touch Screen Display is connected to the Main PCB at connector J5. Data from Processor #1 is sent to a latch U15 where it is then clocked to the display. Information is entered from the touch screen keyboard and is passed through connector J5 to Processor #1. Power is supplied to the display via connector J5 pins 16 & 17 for the +5 VDC and pins 18 & 19 for the +12 VDC. Pins 4,5,20,21,24,29 and 30 are grounded. top of chapter

6-6   Touch Screen Display

The touch screen display assembly consists of four main components: The bezel assembly, touch screen, display and the interface PCB.

The Display is a 320 by 240 dot matrix (15 lines by 40 characters) and is controlled by the display controller U1 (SED133SF) on the interface PCB. The information is presented to the controller in an eight bit parallel format from the Main PCB via processor #1. It is then converted to a video format and sent to the display as pixels.

The touch screen is an Analog Resistive Touch Screen (ARTS). It consists of two layers (one orientated along the X-axis and one layer orientated along the Y-axis) of a transparent resistive film separated by a spacer. The active axis of the screen is selected via two control signals which switch one of two pair of MOSFETS (U4) on to apply a fixed voltage across the axis of the resistive element. The inactive element becomes the input for the A/D convert. R1 is a pull down resistor for the vertical axis and R2 is a pull down resistor for the horizontal axis. When the screen is pressed a unique voltage is generated for both the X layer and the Y layer. These two voltages are converted to a digital

representation of the location on the screen by the A/D converter in Processor #1.   top of chpater

6-7   Readhead System Overview

The Readhead system consists of the following components: Two Pre-amps, an A/D converter subsystem, two independent illumination sources, a drive subsystem and a system controller. The instrument uses two readheads that are spaced to allow for two readings of a strip. The first reading occurs approximately 25 seconds after the strip has been dipped and the second reading at about 67 seconds. Each of the readheads consists of a light source and four detectors. The detectors each have an optical filter that passes a broad bandwidth of energy to the detector. The four bands passed to the detectors are Infrared, Red, Green and Blue. The output of each detector is passed to a two-stage amplifier. (See section 6-9 Pre-amp theory)

The four outputs (IR, Red, Green and Blue) from each of the two pre-amps PCB's are routed to a common A/D PCB. The A/D PCB contains an eight-channel A/D converter that is multiplexed to select which of the eight channels will be converted. Its output is sent in a serial format to Processor #2 (Refer tosection 6-10 A/D theory). Processor #2 controls the operations of reading the strips and calculating the results. Once the results are calculated, they are sent to Processor #1 which controls the User Interface. top of chapter

6-8   Readhead Movement

The two readheads of the CLINITEK® 500 are mounted to a Readhead carrier that rides on a precision ball slide and is driven by means of a stepper motor. The process of taking a reading involves moving this assembly over the reagent strip(s) and scanning each reagent strip taking one or more readings at every pad location. Processor #2 controls the position of the Readhead carrier (See section 6-4-1 motor control theory).

The actual process of reading a strip is summarized below:

The scan cycle is 7 seconds.

1. Strip presence is verified by the strip detector.

2. Processor #2 activates the moving table to advance the reagent strip into the Readhead area. It takes three cycles for a reagent strip placed on the load area to be brought under Readhead #1.

3. If a strip was under Readhead #1 during the previous scan cycle, a control code is sent to processor #2. (A strip is verified as being present at Readhead #1 if the IR channel reflectance between pads 9 and 10, and pads 2 and 3 is above 65% is present in the last data set)

4. If a strip was present at Readhead #2 during the last cycle, the data set, which includes error code, is sent to processor #1. The error flags are reset after the error code is sent. (If both events 3 and 4 occur a code will be sent first)

5. At 3.0 seconds into the 7 second scan cycle, the actual read operation begins:

    A. Move the Readheads to find the edge of the cal-chip under readhead #1 and move to the center of the cal chip. This is arbitrarily set as location 0.

    B. Perform a dark value reading on all channels.

    C. Turn the lamps on and perform a calibration of all channels on the white cal chip.

    D. Move the Readheads out 0.017″ and read each of the eight channels after the Readheads have moved. These readings consist of the A/D converter values associated with each channel. All of the readings are stored in the order taken in temporary memory.

    E. Repeat this until 1488 readings of 2 bytes each are read, dark values subtracted from this and the resultant values stored for each Readhead during the scan cycle.

    F. The Readheads are returned to the cal chip location.

6. Calculations are performed based on the specifics of the reagent strip being tested. Not all data is used in these calculations (for example, for most MULTISTIX reagents, only the reading closest to the center of the reagent pad is used in the determination of results for that analyte).

    Calculations are done to obtain reflectances, which, after processing in the specific algorithm for a reagent, is compared to a decode point, and converted into a reportable clinical level. Each of the interim and final results is stored in the appropriate data set.

    After all individual pad calculations are completed the color calculations are done and stored. The date, time and sequence number, are sent in the data set. The sequence number is then incremented.

7. The system then waits until the 7-second scan cycle is completed. The process then repeats until there are no more reagent strips under the hood area.   top of chapter

Block Diagram of Process of Scanning a Strip

```
        ┌─────────────────────────┐
        │  Strip has been moved   │
        │    under Readhead 1     │
        └────────────┬────────────┘
                     │
                     ▼
  ┌──────────────────────────────┐
  │ Have 12 Cycles occurred      │        YES        ┌───────┐
  │ without detecting a strip    │─────────────────▶ │  END  │
  │ under either readhead        │                   └───────┘
  └──────────────┬───────────────┘
                 │ NO
                 ▼
  ┌──────────────────────────────┐
  │ Readhead #1 finds the edge   │
  │ of the Cal chip, then moves  │
  │ to chip center               │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Read dark values for all     │
  │ channels                     │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Turn lamps on and calibrate  │
  │ all channels                 │
  └──────────────┬───────────────┘
                 │
                 ▼
┌─────────┐  ┌──────────────────────────────┐
│ Cycle   │  │ Scan reagent strip read all  │
│ Moving  │  │ 8 channels (1488 readings    │
│ table   │  │ taken)                       │
└─────────┘  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Readheads return to cal chip │
  │ position                     │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Select readings              │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Calculations performed       │
  │ reflectance, decode,         │
  │ clinical levels              │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Color calculation done date  │
  │ and time stored in data      │
  └──────────────┬───────────────┘
                 │
                 ▼
  ┌──────────────────────────────┐
  │ Wait for cycle to complete   │
  │ and repeat operation         │
  └──────────────────────────────┘
```

Figure 6-4

6-9 Pre-amp PCB

The CT500 has two functionally identical Readheads. The heart of each Readhead is the surface mounted detector package. This device has four separate channels each with its own optical filter: one green, one infrared, one blue and one red. Each of the channels has it's own photo detector output. The output of the detector is passed through a two-stage Pre-amp and its output through connector P1.

The op-amps used on the Pre-amp operate from a +5VDC and -5VDC power supply located on the A/D PCB. When the lamp in the readhead is on and it is over the calibration chip the output of each of the Pre-amp channels should be approximately +4VDC. With the Readhead lamp off, the outputs of the pre-amp channels should be approximately 0VDC (because the op-amps operate from the both a positive and negative supply up to a.4 positive or .4 negative voltage may be observed).   top of chapter

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CAUTION

Cotton gloves must be worn when handling the Preamp PCBs.

ESD percautions must be taken whenever the upper case of the instrument is removed.

A dirty Preamp PCB can cause errors 02-1 and 02-2.

6-10 Pre-amp A/D PCB

The Pre-amp A/D PCB receives the analog signals from both Pre-amp PCBs and converts these voltages to digital values. This count is the raw value that is used in the algorithms to calculate reflectance.

The Analog to Digital conversion is performed by IC U1 an eight channel analog multiplexing A/D converter with serial output. There are also four voltage regulators on the PCB. Voltage regulator VR1 provides a +4 VDC reference for the A/D converter. Voltage regulator VR2 provides the +5 VDC used by both readheads pre-amp PCB and the A/D board. Voltage regulator VR3 provides the −5 VDC used by both readhead pre-amp PCB's and the A/D board. Voltage regulator VR4 provides the + 6 VDC for the lamps in both readheads. Power is supplied to the A/D PCB

from the processor PCB via connector P3; pins 9 &10 provide +12 VDC and pin 6 provides -12 VDC.   top of chapter

6-11 Strip Detector

The strip detector contains 5 high output red LED's and 4 detectors spaced between the LED's. (Presently, the LED at the left of the detector is not used.) Every 100 milliseconds, when the Push Bar is at the left most position, one of the LED's is pulsed ON for about 16 microseconds. The five strip detectors LED's are turned ON one at a time, sequentially from the timer interrupt routine. The LED's are disabled during the time the "Push Bar" is moving or located at the right side.

Light reflected back by the presence of a strip is picked up by an associated detector and triggers a level sensitive circuit connected to an input port on the processor. Each detector has two "detection level-setting" circuits associated with it, one for each of the two LED's with which it operates. The detection levels are calibrated only when the instrument power is turned on, when no strip is on the table (<u>The fixed table needs to be in place when the instrument is powered on for proper detector calibration</u>). For each of the 8 detector-LED pairs, the detection level count is found where light from the table just causes detection. Then the setting is increased by a percentage of the count for low level signals and for high level signal it adds a constant, so that a strip is necessary to cause detection. When the strip detector setup is printed out using the Instrument test card (Refer to section 7-3-4-4) the printout will show the detector calibration values for both of its LEDs

```
Example of Strip Detector Set-up print-out

L1D1  L2D1  L2D2  L3D2

L3D3  L4D3  L4D4  L5D5  L5D5
```

Notice that L5D5 is printed twice. The second calibration level is used for the "Strip Verification" position and has a lower detector gain setting to prevent false verification.

Note

On early units, a 5th LED on the far left may be present but disabled. The Set-Up value L1D1 is calculated but is not used by the software.

The calibration compensates for variations in LED output, detector sensitivity, and table reflectance changes. The strip detector is AC coupled, to reduce the effect of ambient light.

The detector circuits require both +12 volts and – 12 volts for operation which is supplied via connector P1: pin 3 (+12 VDC), pin 2 (-12 VDC) and pins 1, 4 and 5 are ground.

The instrument only calibrates the strip detector during the power on cycle.   top of chapter

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CHAPTER SEVEN – EXERCISE / DIAGNOSTICS TROUBLESHOOTING   *Return*

Section

7-0   Introduction

This chapter is divided into four distinct sections.
Each of the sections has its own table of contents
at its beginning.

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7-1 Troubleshooting table

The following chart is provided to assist in troubleshooting the CLINITEK 500 system. The first three columns are similar to those found in the Troubleshooting Section of the Operating Manual.

The fourth column, labeled "Service Remedy" contains more advanced troubleshooting which should only be performed by / or under the guidance of trained Bayer Service Personnel. The items in the forth column are listed in increasing order of technical difficulty

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Display is blank	No power.	Listen for the fan; if it is not running, turn the instrument power *off.* Check that the power cord is firmly plugged into the instrument and into a live AC electrical outlet. Turn the power back *on.*	Remove the Bezel Assembly and check that all cables are properly seated. (Refer to sections 9-4). Verify input and output voltages to the power supply. (Refer to section 7-4-3-1).
	Improperly inserted program card.	Turn the instrument power *off* then remove the program card and reinsert it firmly, making sure that the label is facing forward, with the arrows pointing in and up. When properly inserted, the edge of the card will be flush with the instrument case. Turn the power back *on.*	Use the instrument test card to verify that the problem is not related to the customers program card. Troubleshoot the Display (Refer to section 7-4-5). Trouble-shoot the Main Processor PCB (Refer to section 7-4-6).
	Defective program card or defective system electronics.	Contact your Bayer Customer Service office.	
Fixed Table can not be installed	The Moving Table is not in the lowest position	Turn power ON and let the system initialize, then switch the power off. Repeat 3 times.	Inspect the Fixed and Moving Tables for damage. Using the Instrument Test Card, test the Drive Housing and stepper motor for proper operation.
Printout does not contain all reports	"Missing" reports have been flagged for confirmatory report, and "Edit" flagged result is ON	The list of the flagged reports will be displayed when the run is complete and the report will be printed after the End-of-Run Report screens have been exited.	Perform printer tests using the Instrument Test Card. (refer to section 7-3-4-2)

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Push bar does not move to the right after a strip is placed onto the platform.	Other strips are being moved along the platform.	Allow up to 7 seconds to elapse before movement of the push bar. The time lapse depends upon the timing cycle for movement of the strips across the platform.	Verify that the Strip Detector LEDs are turning on. Verify that the customer's system is in the Ready/Run state. Check that the cable from the push arm motor is seated into connector P14 on the mother PCB.
	Strip Detector problem.	From the Ready/Run screen (and with the run complete), turn the instrument power off, wait several seconds, then turn it back on. If the problem continues, contact your Bayer Customer Service office.	Use the instrument test card to check operation. (Refer to section 7-3-6-3). Verify strip detector operation (Refer to section7-3-4-4). Verify that the strip detector has correct voltages (Refer to section 7-4-3-2). Replace the strip detector (Refer to section 9-14). Trouble shoot the MAIN PCB for a broken trace and replace if necessary (Refer to section 7-4-6).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Push bar does not move back to the left after moving a strip (other than at the end of a load-listed run or while waiting for entry of an ID).	The last strip has been placed in a loadlist run, or the instrument is waiting for entry of an ID. A very dark urine is being tested; the strip detector is unable to verify the presence of the strip until it reaches the first readhead.	The instrument is functioning properly. Begin a new loadlist run (after the current run is complete) or enter the ID Number being requested. Presence of the strip will be verified at the first readhead, requiring an additional 3 cycles (21 seconds). The push bar should then move back to the left. Continue testing in the normal manner.	If occurs repeatedly or occurs with non-dark urines, verify proper Strip Detector operation as outlined below. Verify that the Strip Detector LEDs are turning on. Use the instrument test card to check operation (Refer to section 7-3-6-3). Verify strip detector operation (Refer to section7-3-4-4). Verify that the strip detector has correct voltages (Refer to section 7-4-3-2). Replace the strip detector (Refer to section 9-14). Trouble shoot the MAIN PCB for a broken trace and replace if necessary (Refer to section 7-4-6). Check that the cable from the push bar motor is seated into connector P14 on the mother PCB Defective push bar mechanism – troubleshoot (Refer to section 7-3-6-3 and 9-18).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Push bar moves to the right when it shouldn't (a strip has not been placed on the platform)	The strip detector was accidentally triggered by a hand, sleeve or other foreign object.	The push bar will move back to the left after 3 cycles (21 seconds); continue testing in the normal manner. Be sure you do not place your hand or other objects on the platform, as these can be mistaken for a Reagent Strip.	Verify that the Strip Detector LEDs are turning on. Use the instrument test card to check operation. (Refer to section 7-3-6-3). Verify strip detector operation (Refer to section7-3-4-4).
	Ambient light has changed significantly	From the Run/Ready screen (with the run completed and the strip loading station clear of all strips and foreign objects), turn the instrument power *off*, wait several seconds, then turn it back *on* to recalibrate the strip detector. If the problem continues, contact your Bayer Customer Service office	Verify that the strip detector has correct voltages (Refer to section 7-4-3-2). Replace the strip detector (Refer to section 9-14). Troubleshoot the MAIN PCB for a broken trace and replace if necessary (Refer to section 7-4-6).
	Strip detector problem.		
Test results are not being printed by the internal printer	Internal printer is set to OFF.	Set the internal printer to ON through the Setup Routine (Refer to section 3, Step A-4).	Verify that all cables are properly seated. Verify that the internal printer has power. (Refer to section 7-4-3-3). Perform printer tests using the instrument test card on both internal and external printers. (Refer to section 7-3-4-2). Clean internal printer drive mechanism with isopropyl alcohol and cotton tip applicator or equivalent. (Refer to section 8-4). Replace internal printer (Refer to section 9-3) Replace printer driver PCB Main PCB (Refer to section 9-11). Mother PCB (Refer to section 9-13).
	No paper installed in printer.	Install a new roll of paper as instructed in Section 5, "Periodic Maintenance."	
	Paper installed backwards or incorrect paper beiing used.	Remove the paper and install per the direction of the Operating Manual. Use only Bayer thermal printer paper.	
	Loose electrical connection to the printer.	Carefully remove and reinstall the interface cable to the printer (See section 7, "Printer Replacement," steps 4 and 5).	
	Defective printer.	Run the printer test (see Section 3, Step J-2f). Contact your Bayer Customer Service office if it does not print correctly.	

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Touch Screen does not respond correctly	Screen needs to be recalibrated. Defective screen.	Recalibrate as instructed in Section 7, "Calibrating the Touch Screen" of the Operating Manual. Contact your Bayer Customer Service office.	Refer to Figure 7-1-1 for detailed troubleshooting flowchart. Reset instrument to default settings (Reference Operating Manual chapter 3 section J). Install Instrument Test Card and recalibrate touch screen. Remove the Bezel Assembly and check that all cables are properly seated. (Refer to sections 9-8). Verify input and output voltages to the power supply. (Refer to section 7-4-3-1). Use the instrument test card to verify that the problem is not related to the customers program card. Troubleshoot the Touch Screen (Refer to section 7-4-5) Troubleshoot the Main Processor PCB (Refer to section 7-4-6)
Error 01 Error 02 Error 03 Error 04 Error 05	Instrument optical error.	Turn the instrument power *off*, wait several seconds, then turn it back *on.*	Problem with the pre-amp or A/D PCB (Refer to section 7-2-2). Troubleshoot Readhead subassembly (Refer to sections:7-4-1, 7-4-2, 7-3-5-1 and 7-3-5-2). Replace BOTH Lamps (Reference 9-15). Replace Pre-amp (Refer to section 9-16-2). Replace A/D PCB (Refer to section 9-16-1).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 06-2	A reagent strip that had been detected at the first readhead was not detected at the second readhead.	Touch the Return to Ready/Run button to cancel the run and return to the Ready/Run screen, then turn *off* the instrument power. Remove Push Bar and the Fixed Table to locate the strip (Refer to section 5, "Daily Cleaning"). Check the pins on the Moving Table to ensure that none are bent or broken. Perform the "Daily Cleaning" and "Weekly Cleaning" procedures in section 5. Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results; retest those specimens.	Verify that Fixed Table seats correctly (Refer to section 9-5). Verify that Moving Table seats correctly (Refer to section 9-6). Perform Strip Walk Test (Refer to section 7-3-3-6). Replace Drive housing (Refer to section 9-17). Replace Fixed Table and Moving Table (Refer to section 9-5, 9-6). Replace Table Guides (Refer to sections 9-8, 9-9).
Error 07-1	A reagent strip either is not fully wetted or is upside-down on the platform.	If the error is because of an upside-down strip, remove and clean the Push Bar, Fixed Table, and Holddown (see Section 5, "Daily Cleaning"). Then check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results. Retest the appropriate specimen, ensuring that the strip is dipped completely into the specimen and is placed onto the platform with the pads facing up.	Inspect Push Bar, Fixed Table and Holddown for physical damage. Replace as necessary. (Refer to section 9-1, 9-5, 9-6).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 08-1 Error 08-2	A Reagent Strip has become misaligned during processing due to the tip of the strip "walking" closer to the cal chip or farther away from the cal chip. This error indicates that a strip position correction factor of 0 or 8 was determined for readhead 1 or readhead 2 .	Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results. Retest those specimens, ensuring that the end of the strip is placed against the rear wall of the platform (with Error 08-1) and not touching the bottom of the strip loading station. If the error repeats, remove and clean the Push Bar, moving table, Fixed Table, Holddown, (see section 5, "Daily Cleaning") Check the Moving Table to ensure that no pins are bent or broken, then reinstall the parts. Make sure that the tables are fully seated and that the Holddown is snapped into place.	Inspect Push Bar, Fixed Table and Holddown for physical damage. Replace as necessary (Refer to section 9-1, 9-5, 9-6). Make sure that the instrument is level. Verify that Fixed Table seats correctly (Refer to section 9-5). Verify that Moving Table seats correctly (Refer to section 9-6). Perform Strip Walk Test (Refer to section 7-3-3-6). Realign horizontal table (Refer to section 8-3). Replace Drive Housing (Refer to section 9-18). Replace Fixed Table and Moving Table (Refer to section 9-5, 9-6). Replace Table Guides (Refer to section 9-8,9-9). Check that drive housing flag is positioned in sensor (Refer to section 8-6).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 09-1 Error 09-2	A Reagent Strip has become skewed during processing	Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results. Retest those specimens, ensuring that the end of the strip is placed against the rear wall of the platform and not touching the bottom of the strip loading station. If the error repeats, remove and clean the Push Bar, moving table, Fixed Table, Holddown, (see section 5, "Daily Cleaning") Check the Moving Table to ensure that no pins are bent or broken, then reinstall the parts. Make sure that the tables are fully seated and that the Holddown is snapped into place.	For Error 09-1, have customer check to see if reagent strips have stacked up near the outfeed area in the waste bin. If so, clear any jams and push strips to right in waste bin to clear the outfeed area Inspect Push Bar, Fixed Table and Holddown for physical damage. Replace as necessary (Refer to section 9-1, 9-5, 9-6). Make sure that the instrument is level. Verify that Fixed Table seats correctly (Refer to section 9-5). Verify that Moving Table seats correctly (Refer to section 9-6). Perform Strip Walk Test (Refer to section 7-3-3-6). Realign horizontal table (Refer to section 8-3). Replace Drive Housing (Refer to section 9-18). Replace Fixed Table and Moving Table (Refer to section 9-5, 9-6). Replace Table Guides (Refer to section 9-8,9-9). Check that drive housing flag is positioned in sensor (Refer to section 8-6). .

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 10 –1 10 –2	Instrument optical error.	Turn the instrument power *off*, then remove and clean the Fixed Table, taking care to carefully clean the calibration bars (see Section 5, "Daily Cleaning"). Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results; retest those specimens.	Troubleshoot Pre-amp subassembly (Refer to sections: 7-4-1, 7-4-2, 7-3-5-1, 7-3-5-2). Replace Pre-amp (Refer to section 9-16-2). Replace A/D PCB (Refer to section 9-16-1).
Error 20-1 NOTE: This error only applies to Kanjii units.	The instrument was not able to automatically detect the strip type (if "Auto Detect" has been selected through the Setup Routine). (Refer to section 3, Step C).	Ensure that you are using a recognized strip type Retest the specimen using a new strip. If the error continues to occur, contact your Bayer Customer Service office.	Troubleshoot Pre-amp subassembly (Refer to sections: 7-4-1, 7-4-2, 7-3-5-1 and 7-3-5-2). Replace Pre-amp (Refer to section 9-16-2). Replace A/D PCB (Refer to section 9-16-1).
Error 21	Internal memory error	Turn the instrument power *off*, wait several seconds, then turn it back *on.*	Replace program card. Replace Processor #1 module (Refer to section 9-11-1). Replace Main PCB (Refer to section 9-11).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 23	Moving Table is misaligned Instrument mechanical error	Turn the instrument power *off*. Check to see if the moving table is installed. Inspect the instrument for any obvious signs of misalignment or incorrect installation of the moving table or fixed table. Remove and reinstall the fixed and moving table, see Section 5, "Daily Cleaning." Turn the power back *on*. Contact your Bayer Customer Service office.	Inspect Drive Housing and Fixed Table Guides for wear or damage. Replace as necessary. (Refer to section 9-5, 9-6, 9-8,9-9, 9-18). Verify that moving table is aligned correctly (Refer to section 8-3). Verify that optical sensor operate correctly (Refer to section 7-4-4). Check stepper motor drive circuits for proper operation (Refer to section 7-4-3-4). Use instrument test card to cycle motors (Refer to section 7-3-3-2 and 7-3-6). Replace Mother PCB if defective (Refer to section 9-13).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 24	Misalignment or incorrect installation of the push bar or fixed table	Turn the instrument power *off*. Inspect the instrument for any obvious signs of misalignment or incorrect installation of the push bar or fixed table. Remove and reinstall, if needed, as directed in Section 5, "Daily Cleaning." Turn the power back *on*.	Push Bar is not finding home in the proper time. Verify that optical sensor operate correctly (Refer to section 7-4-4) Check stepper motor drive circuits for proper operation (Refer to section 7-4-3-4).
	Instrument mechanical error	Contact your Bayer Customer Service office.	Use instrument test card to cycle motor (Refer to section 7-3-3-2 and 7-3-6). Clean Push Bar Shaft and lubricate (Refer to section 5-5-3). Replace Mother PCB if defective (Refer to section 9-13). Check to see that left-hand PREAMP PCB is not hitting any of the mechanical assemblies as the readheads move back and forth while cycling all motions. If hitting, carefully loosen the screw holding the PREAMP, lift up on the rear end of the PCB and retighten screw.

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 25	Readhead could not find the Cal Chip. Instrument mechanical error	Turn the instrument power *off.* Inspect the instrument for any obvious signs of misalignment or incorrect installation of the Fixed Table, or Holddown. Remove and reinstall, if needed, as directed in Section 5, "Daily Cleaning." Turn the power back *on.* Contact your Bayer Customer Service office.	For error 25, perform 3 on/off cycles of instrument power, ignoring any errors received prior to the 3rd cycle. Check to see that left-hand PREAMP PCB is not hitting any of the mechanical assemblies as the readheads move back and forth. If hitting, carefully loosen the screw holding the PREAMP, lift up on the rear end of the PCB and retighten screw. Check that Flex cable is fully seated in connector J7 on Main PCB. Insure that flex cables are fully seated in the connectors on the Preamp PCB's and that the lamp cables are locked in place on the A/D PCB. Verify that the lamps operate, replace if necessary. (Refer to section 7-3-5-1, 9-15) Test Preamp operation by positioning readheads over cal chips and obtaining A/D counts (Refer to section 7-3-5-2). Replace Preamp (Refer to section 9-16-2). Check stepper motor drive circuits for proper operation (Refer to section 7-4-3-4). Use instrument test card to cycle motors (Refer to section 7-3-3-2 and 7-3-6). Replace Mother PCB if defective (Refer to section 9-13).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 26	Fixed Table is missing or not installed properly.	Install the table and platform, if missing (see Section 5, "Daily Cleaning"). If already installed, carefully push in on the sides of the platform to make sure it is fully engaged. If the error continues, remove and reinstall the platform, as instructed in Section 5.	Inspect Drive Housing and Fixed Table Guides for wear or damage. Replace as necessary (Refer to section 9-5,9-6,9-8,9-9, 9-18). Verify that all connectors are seated. Use instrument test card to test individual sensors. (Refer to sections 7-4-4). Confirm that the Fixed Table enters the photo sensor on the table guide. (refer to section 8-5 for adjustment) Replace sensor as necessary MOTHER PCB defective replace (Refer to section 9-13). Processor #1 is defective on the MAIN PCB - Replace (Refer to section 9-11-1).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 27	Holddown is improperly installed,or missing, or is dirty.	Touch the Return to RUN/READY button if necessary to cancel the run. Remove the Fixed Table as instructed in Section 5, "Daily Cleaning." Install the Holddown if missing, or clean if it appears dirty. Reinstall the Holddown, ensuring it is properly installed, then replace the platform onto the instrument (if the Holddown appears damaged or discolored, replace with a new Holddown). Check your printout of results, or the Results Error Report displayed at the end of the run, to determine the specimen(s) for which there are no results and retest those specimens.	Refer to section 7-2-2-1. Inspect Fixed Table and Holddown for wear and discoloration. Replace as necessary (Refer to section 9-5).

Verify Readhead performance and alignment (reference 7-3-5-3, 8-2) |

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 28	A Reagent Strip that was detected, as being placed on the platform, was not detected at the first readhead.	A strip was never placed or was removed after being placed: Check your printout of results, or the Results Error Report displayed at the end of the run, to determine if a result set is missing and, if so, retest the specimen. Be sure you do not place your hand or other objects on the strip loading station, as these can be mistaken for a Reagent Strip. If the error occurs repeatedly, turn the instrument power *off*, wait several seconds, then turn it back *on* to recalibrate the strip sensor. If a strip was present, remove and clean the Moving Table, Fixed Table, Holddown (Reference operating manual section 5, "Daily Cleaning" and "Weekly Cleaning").	Refer to section 7-2-2-1. Confirm strip detector operates properly using instrument test card (Refer to section 7-3-3-4). Verify that the cable coming from the strip detector has its connector properly seated into the mother PCB. Replace the strip detector (Refer to section 9-14). Check for proper readhead performance by running reflectance test with instrument test card. (Refer to section 7-3-5-4) Replace Pre-amp PCB (Refer to section 9-16-2).
	Moving Table is not installed.	Remove the Fixed Table and check for the presence of the Moving Table. If missing install.	

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 29	Calibration bar error.	Turn the instrument power *off,* then remove the Fixed Table (see Section 5, "Daily Cleaning") and inspect the calibration bars for damage or misalignment. Clean the platform and calibration bars and reinstall the platform. Turn the power back *on.*	Refer to section 7-2-2-1. Make sure that the customer has installed the fixed table completely (to the stops). Cycle instrument power on/off three times ignoring any errors reported prior to the 3rd cycle. Check for damage to the Fixed Table cal chips. Use the instrument test card to verify stepper motor drive operation for readhead carrier and that carrier is moving with the belt. (Refer to section 7-4-3-4, 7-3-6- Remove upper case and verify that all connectors (signal and lamp) on the readhead and A/D PCB are fully seated. Verify that the lamps turn on. Use instrument test card to verify operation of Pre-amps and A/D PCB (Refer to section 7-3-5-1, 7-3-5-3, 7-4-1, and 7-4-2).
Error 30	Instrument mechanical error (Readhead alignment error)	Contact your Bayer Customer Service office.	Refer to section 7-2-2-1. Make sure that the customer has installed the fixed table completely (to the stops). Error 30-check alignment of readheads (Refer to section 8-2). Check for proper operation of Pre-amps & A/D PCB's.(Reference 7-3-5-3)

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 31	Instrument mechanical error. (Strip Detector Set Up Error)	Contact your Bayer Customer Service office.	Refer to section 7-2-2-1. Make sure that the customer has installed the fixed table completely (to the stops) Error 31-verify strip detector operation (Reference 7-3-4-4).
Error 34	Instrument mechanical error (Strip Centering Error / instrument factor error)	Contact your Bayer Customer Service office.	Refer to section 7-2-2-1. Make sure that the customer has installed the fixed table completely (to the stops). Perform strip centering test (Reference 7-3-3-4).
Error 40	Not an assigned error for the customer software.	Verify that the proper software is installed.	Communications error between processor #1 and processor #2. Replace processor #1 (see Section 9-11-1). Replace MAIN PCB (see section 9-11).
Error 50	Printer Error	Check that your external printer is turned on and is on-line. Verify that both ends of the interface cable are securely connected and check that your printer has paper	Re-verify proper installation of interface cable. Possible defective Printer Mother PCB (see Section 7-3-4-2, 9-13). Possible defective Printer Cable. Possible defective MAIN PCB (see Section 9-11).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 51 Error 52	Control results memory (51) or sample results memory (52) is almost full.	Nearly 200 control result sets or nearly 500 patient results sets have been stored in memory without being transferred to a computer. Check that your computer is turned on, that the interface cable is securely connected at both ends, and that the setup parameters for the computer interface are correct. Transfer at least some of the record. If unable to transfer records, print the records and then delete the results from memory. Contact your Bayer Customer Service office	Verify that customer setup is correct Verify that CT500 External Port is turned ON Verify that external computer is connected to the serial communication RS 232 port Possible defective Mother PCB (See section 7-3-4-1, 9-13) Possible defective MAIN PCB (See section 9-11)
Error 53 Error 54	Control results memory (53) or sample results memory (54) is completely full	Two hundred control result sets or 500 patient results sets have been stored in memory without being transferred to a computer. Check that your computer is turned on, that the interface cable is securely connected at both ends, and that the setup parameters for the computer interface are correct. Transfer at least some of the record. If unable to transfer records, print the records and then delete the results from memory. Contact your Bayer Customer Service office.	Verify that customer setup is correct Verify that CT500 External Port is turned ON Verify that external computer is connected to the serial communication RS 232 port Possible defective Mother PCB (See section 7-3-4-1, 9-13) Possible defective MAIN PCB (See section 9-11)
Error 55	System was unable to store Setup changes to the Program Card; default values have been stored instead. Displayed when Analyzer is first turned *on*.	After clearing the error screen, print both setup configurations, if desired, to determine which you want to use, then select that option. (the Analyzer memory will usually contain the latest Setup changes). If the error repeats the next time the instrument is turned on, contact your Bayer Customer Service office.	Possible defective program card (see section 9-2). Possible defective MAIN PCB (see section 9-11).

Symptom or Error Displayed	Possible Cause	Customer Remedy	Service Remedy
Error 56	System error	Turn the instrument power *off*, wait several seconds then turn it back *on*. If the error repeats, contact your Bayer Customer Service office.	General error code for internal communications errors. Possible defective Processor #1 (See section 9-11-1). Possible defective MAIN PCB (See Section 9-11). Possible defective program card (see section 9-2).

Failure Identification Flow Chart For Display and Touch Screen Problems

No problem	
Report Error: DT006	
Cycle power and recalibrate touch screen.	
Report Error DT007	
Report Error: **DT008**	
Report Error: **DT009**	
Trouble shoot Per Service Manual Report Error: DT010	
Trouble shoot Per Service Manual Report Error: DT011	

Is display operating correctly? — NO → Is the Display Blank? — YES → Trouble shoot per service manual. Report error: DT001

YES → Is touch screen responding?

Is the Display Blank? — NO → Are lines scrolling on the screen? — YES → Display Bad Report Error: DT002

NO → Is character string correct? — YES → **No problem**

NO → Cycle power. Does the problem correct itself? — YES → Problem corrected Report error: DT003

NO → **Perform the following**
1) **Print out instrument set up.**
2) **Reset the customer settings to the instrument defaults**
— YES → Report Error: DT015

NO → **Perform the following**
1) **Reset memory with Instrument test card.**
2) **Reset the customer settings to the instrument defaults.**
Is the problem corrected?
— NO → Trouble shoot Display, Main PCB and Program Card.

Report Error: DT005

YES → Problem corrected Report Error: DT004

Is touch screen responding? — NO → Do adjacent areas around the keys respond? — YES → Cycle power and recalibrate touch screen. (YES → Report Error: DT006, NO → Report Error DT007)

Do adjacent areas around the keys respond? — NO → Cycle Power. Does touch screen respond? — YES → Report Error: **DT008**

NO → Cycle power and recalibrate touch screen. Does touch screen — YES → Report Error: **DT009**

NO → Is Pusher Bar to the left? — NO → Trouble shoot Per Service Manual Report Error: DT010

YES → Will strip detector detect strip and cycle pusher bar — NO → Trouble shoot Per Service Manual Report Error: DT011

YES → Does the Display update to run mode — NO → System Locked up Report Error: DT012

YES → Does Data Print — NO → Report Error: DT013

YES → Replace touch Screen Report Error: DT014

Figure 7-1-1   top of chapter

7-2 Explanation of Error Codes

7-2-1 Error Handling

The Errors on the instrument are divided into:
1) General Errors
2) Data Set Errors.

A General Error is defined as an error resulting from hardware input, e.g., a ROM checksum Error, RAM checksum error, Processor #2 programming error or a sensor error. These errors are detected by processor #2.

A Data Set Error is defined as an error detected by analyzing the data collected from the readheads during the read process.

7-2-1-2 Error Number Display

The Instrument Test Card and Customer Card display only those errors defined as "general errors" on the screen. These general errors are generated by processor #2 as a two-digit number and sent to processor #1 to display on the screen (refer to Table 7-2-1 for complete listing).

```
The Analyzer has reported Error N-XX
```

Figure 7-2-1

7-2-1-3 Error Numbers Printed

The Data Set errors are printed or sent with the data sets. The Data Set errors are displayed in different forms depending upon if an Instrument Test Card is being used or the Customer Card. When the Customer Card is installed in the instrument, the error code will be printed or displayed on the screen (see figure 7-2-1) as 1-xx or 2-xx. The first digit

represents the readhead associated with the error and the "xx" is the two-digit error code..

When the Instrument Test Card is installed in the instrument, the error code is a four-digit code. The first two digits are the error code for the first readhead and the second two digits are the error code for the second readhead (see figure 7-2-2).

The two digits to the right of "POS:" are the strip tip locations. The first digit is the location of the strip under the first readhead with respect to the first calibration chip and the second digit is the strip tip location under the second readhead as compared to the second calibration chip.

Table 7-2-2, in the section 7-2-2, is a listing of Data Set error codes and their meanings as well as a cross-reference between the error codes generated from the Customer Card and the Instrument Test Card.
Note that the error codes in the sample output (Figure 7-2-2) can combine based on column

First readhead error code

Second Readhead error code

```
#00008 19940426125800
ERRORS: 0000     POS: 34
COL      A   B    L    CD
       -020 +014 +209 +002
SRV   I   R   G   B   DCD
GLU 787 793 809 074 0744
BIL 737 663 457 124 0900
KET 785 752 685 432 3847
SG  727 692 322 112 5061
pH  125 041 026 067 0562
PRO 618 588 589 767 0790
URO 322 322 316 242 0980
NIT 063 096 053 530 0836
BLO 024 045 056 124 0900
LEU 820 771 560 355 5612
LE1 637 698 876 907 7500
```

Figure 7-2-2

position (for non zero columns) and error code priorities in Table 7-2-2.

Note

This means that only the higest piroty erors will be displayed even if mutipal error exist.

For example, if the system detects both a "skewed strip" error on RH #2 (Error Code 0009) and a "reflectance > 100%" on RH #2 (Error Code 0010), the error reported in Figure 7-2-2 might be "0018". If the system generates a "Low Dark Value" error

for RH #1 (Error Code 0100) and a "Missing Strip" error for RH #2 (Error Code 0006) then the error code output would be "0106". However, if the system generates two errors with digits in the same column only the higher priority error is displayed. For example, a "Reflectance > 100%" error on RH #1 (Error Code 1000) and a "Auto Strip Type Error" on RH #1 (Error Code 2000), then the system will output Error Code "2000" since the Auto Strip Type error (Priority = 10) is a higher priority error then Reflectance (Priority = 11).

7-2-2 Error Summary

Table 7-2-1

General Error Codes

Instrument Test Card Error Definition	Error Code Generated	Customer Card Error Definition
ROM Checksum Error	21	ROM Checksum Error
Table Movement Error	*23	Table Movement Error
Push Bar Movement Error	*24	Push Bar Movement Error
Read-head Scan Movement Error	*25	Read-head Scan Movement Error
Table Not in Place	26	Table Not in Place
Hold-downs Not in Place	*27	Hold-downs Not in Place
False Strip Detect	*28	False Strip Detect
Cal Chip NOT Found Error	29	Cal Chip NOT Found Error
Read-head Alignment Error	*30	Read-head Alignment Error
Strip Detector Setup Error	31	Strip Detector Setup Error
(unassigned)	32	(unassigned)
(unassigned)	33	(unassigned)
Strip Centering Error	34	Strip Centering Error
Communication	40	(unassigned)
(unassigned)	50	Printer error
(unassigned)	51	Control results memory is almost full
(unassigned)	52	Sample results memory is almost full
(unassigned)	53	Control results memory is completely full
(unassigned)	54	Sample results memory is completely full
(unassigned)	55	System was unable to store Setup changes in program card
(unassigned)	56	System error
**Special Instrument Release Test Data Set Errors	61 thru 93	

Notes:
   *Indicates that these error are checked for and reported only during a run
** Refer to table 7-2-2-1
   Refer to section 7-3 Trouble shooting guide for corrective actions

7-2-2-1 General Errors

ROM Checksum Error (21)

If the calculated checksum for the ROM does not equal 0, then this error is set.

Table Movement Error (23)

The table sensor is checked for "no sensor" at 2.5 seconds into the cycle when the table flag should not interrupt the optical sensor and again after 3.0 seconds in the cycle for "sensor present" when the table flag should interrupt the optical sensor. If either condition fails, the error is set.

Push Bar Movement error (24)

The push bar sensor is checked for "no sensor" at about 2.5 seconds in the cycle if the Push Bar was to move and again at about 3.8 seconds when it should be at the sensor. If either condition fails, the error is set.

Readhead Scan Movement Error (25)

This error is set in RUN, during readhead position initialization, when the readhead is not positioned on the cal chip as it should be.

Table Not In Place (26)

The table sensor is not activated.

Holddowns Not In Place (27)

When a strip is read at the first readhead, the reflectance between pads 10 and 11 is checked (this is actually between the tip of the strip and the calibration chip). If no reflectance reading is below 40%, the error condition is set. (With the hold-downs in place the reflectance is on the order of 15% to 20% and with no hold-downs it is above 80%).

False Strip Detect (28)

If a strip is detected and verified by the strip detector but is not sensed as being present at the 1st readhead when it should be, this error is set. A strip is sensed as being present as follows: Two areas of the strip are checked, between pads 2 and 3 and between pads 9 and 10.. If both areas did NOT have a reading >65%, the false strip detect error is set.

Cal Chip NOT found error (29)

During initialization of the readhead position, either at power ON or during RUN, the cal chip under readhead 1 could not be found (IR reflectance <50%) by moving IN up to 750 steps.

Read-head Alignment error (30)

The stored IR readings for each readhead are tested starting with the 1st IR reading in the read buffer, which is near the cal chip center. The cal chip edge is, defined as the first reading below 50% reflectance and the number of motor steps counted. The postion of the cal chip edge for readhead 2 is compared to that of readhead 1. If readhead 2 varies more than ± 3 motor steps then this error is set.

NOTE:

During the strip read operation, readings are stored beginning with position 10 (10 motor steps out from the cal position) and a complete set of readings is stored every four steps thereafter or every 0.01716".

Strip Detector Setup error (31)

When the strip detector "detection level circuit" is calibrated, if the level count was not between 10 and 254, inclusive, this error is set. A high count indicates that there was too much light reflecting from the table or that there was a circuit malfunction..

Instrument Factor / Strip Centering error (34)

This error is generated when the 2-digit Strip Centering step factor is not within the range of 04 to 40 for either readhead or if the difference between the factor for each readhead is greater than 10.

Internal Communications Error (40)

An error occurred in the communication between the two processors

The following error codes definitions are only for the Customer Program Card

Printer Error   (50)

The external printer has an error, or is out of paper.

Control Results Almost Full   (51)

The Controls database has space left for only 10 more results.

Sample Results Almost Full   (52)

The Sample database has space left for only 10 more results.

Control Results Full   (53)

The Controls database is full, no more samples can be run.

Sample Results Full   (54)

The Sample database is full, no more samples can be run.

Setup Information Problem   (55)

One of the setup information files was found to be corrupted during the data integrity check at power ON

System Error   (56)

A serious system error has occurred. The system must be powered OFF. All communication problems between Processor 1 and Processor 2 are reported as system errors.

Special Instrument Release Test Errors *(Only when generated while using the Instrument Test Card)*   **(61 to 90)**

When the instrument release test is performed, data is collected from each readhead and evaluated against ten error conditions. Normally no error is found and the data is transmitted. If an error is detected during evaluation, one of the error codes from the table 7-2-2-1 below will be printed out on the instruments internal printer. When a data set error is detected no data will be sent out the serial port to the computer that is running the Release Test Data Collection software.

The definitions of these errors are the same as the

Table 7-2-2-1
Special Instrument Release Test Errors

ERROR	Generated Error Code	
	RH1	RH2
Low Dark Value	61	81
High Dark Value	62	82
A/D Converter Over Range	63	83
Low Lamp Level	64	84
Low Channel Output	65	85
Missing Strip	(NA)	86
Upside-down / Dry Strip	See note 1	See note 1
Misaligned Strip	68	88
Skewed Strip	69	89
Reflectance > 100%	70	90
Auto Strip Type Error	See note 1	See note 1
Result Data Intergrity	(NA)	93

Notes
1) These error are not checked while the instrument is performing the release test

data set error described in section 7-2-2-2.

Table 7-2-2
Data Set Error Codes

Error	Priority	Instrument Test Card Error Code		Customer Card Error Code	
		Readhead 1	Readhead2	Readhead 1	Readhead2
Low Dark Value	3	0100	0001	01-1	01-2
High Dark Value	2	0200	0002	02-1	02-2
A/D Converter Over Range	4	0300	0003	03-1	03-2
Low Lamp Level	5	0400	0004	04-1	04-2
Low Channel Output	6	0500	0005	05-1	05-2
Missing Strip	7	N/A	0006	N/A	06-2
Upside-down / Dry Strip	12	0700	N/A	07-1	N/A
Misaligned Strip	9	0800	0008	08-1	08-2
Skewed Strip	8	0900	0009	09-1	09-2
Reflectance > 100%	11	1000	0010	10-1	10-2
Auto Strip Type Error	10	2000	N/A	20-1	N/A
Result Data Intergrity	1	N/A	0030		

7-2-2-2 Data set Errors

Low Dark value RH.1 RH.2 (0100) (0001)

A dark value is < 1 count for any channel.

High Dark value RH.1 RH.2 (0200) (0002)

A dark value is >= 400 counts on any channel.

Read Overrange RH.1 RH.2 (0300) (0003)

A-D Converter Overrange. A read value is at full scale (i.e. > 2040 counts) on any channel.

Low Lamp Output RH.1 RH.2 (0400) (0004)

Low Lamp Level. All channels read < 200 counts above dark value at calibration.

Low Channel Output RH.1 RH.2 (0500) (0005)

Low Channel Output. One or more channels on a readhead, but not all, read < 200 counts above dark at calibration.

Missing Strip R.H1 R.H2 (NA) (0006)

Two areas of the strip are checked, between pads 2 and 3 and between pads 9 and 10. If both areas did NOT have a reading >50%, the "missing strip" error is set.

Upside-down or Dry Strip RH.1 RH.2 (0700) (NA)

Reflectance reading was > 70% for the GLU pad on the RED channel or the reflectance reading was > 76% for the LEU1 pad on the GREEN channel. Both are at the 1st readhead.

NOTE:

This is the only error generated using a pad reflectance.

	RH.1	RH.2
Misaligned Strip	**(0800)**	**(0008)**

When doing the strip position correction, the end of the strip nearest the cal chip is located by finding the position where the reflectance goes above 30% as the readhead moves toward the front of the instrument. Steps are counted and a number of "0" through "8" is assigned indicating relative position for each readhead. A number "4" is the nominal position where the strip is in perfect alignment. A smaller number indicates the strip is closer to the cal chip, a larger number shows it is farther. If the number is "0" or "8", the error code for that readhead is set. The positions "1" through "7" will result in correct reflectance for the strip. Each digit indicates a shift of 0.01716 inchs so that correct readings will be obtained for shifts of

±0.051 inchs

	RH.1	RH.2
Skewed Strip	**(0900)**	**(0009)**

The reflectance in the areas between pads 2 and 3 and between pads 9 and 10 are scanned through 8 step positions. If a reflectance is >65% at one area but <65% in the other area, this error is set.

	RH.1	RH.2
Reflectance >100%	**(1000)**	**(0010)**

The reflectance for any pad on the strip measures more than 100%. This may be due to a bad calibration value.

	RH.1	RH.2
Auto Strip Type error	**(2000)**	**(NA)**

If the strip type is set to Japan Auto Strip, then the strip type being used is determined by checking for the GLU pad (reflectance <55%) at one of the two positions for the two supported strip types - MULTISTIX 10 SG and URO-HEMACOMBISTIX SG L. If neither of these were <55%, this error is set. This error code is also reported when a test RUN has commenced with one reagent strip type and a different reagent strip type is detected during the RUN. Although the CT500 supports the auto-detection of the MULTISTIX 10 SG reagent strip and the URO-HEMACOMBISTIX SG L reagent strip, the CT500 does not supporting "mixing" these strip types during a RUN. A RUN may only consist of one reagent strip type.

	RH.1	RH.2
Result Data Integrity	**(NA)**	**(0030)**

The integrity of the results data can not be guaranteed. The checksum sent by Processor 2 did not match the checksum calculated by Processor 1.   top of chapter

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7-3 Explanation of Instrument Test Card

7-3-0 Introduction

The Instrument Test Card is a special program card used during the manufacturing and servicing of the CLINITEK® 500. The following section of the manual explains the function of each test.

 To use this test card, first turn the instrument power off, then remove the Customer Program Card (all customer setup options are saved in this card). Next, insert the test card into the program card socket. When the instrument power is turned back ON, the test software will start.

```
        CLINITEK 500

    INSTRUMENT TEST PROGRAM

Copyright 1997 Bayer Corporation
```

Power ON message:

Following the startup screen if the touch sscreen is not calibrated, the user will be prompted to calibrate the touch screen by pressing the areas indicated on the following screens.

```
+    TOUCH SCREEN HERE




        CALIBRATE THE TOUCH SCREEN
```

```




        CALIBRATE THE TOUCH SCREEN



                    TOUCH SCREEN HERE +
```

When the program card is first installed, the instrument compares the software version in in the card for processor 2 with that running processor 2. If the software versions do not match, the two version numbers will be displayed and the system will prompt " Reprogram Processor #2". Pushing the "YES" key on the touch screen reprograms the processor while pushing the "NO" key does not.

```
Processor #2 version is: AAAAAA
The new card version is: BBBBBB
Reprogram Processor #2?




    YES


    NO

```

AAAAA: Represents the version o processor #2 software being used by the instrument.

BBBBB: Represents the version of processor #2 software on the PCMCIA card.

7-3-1 Self Checks

After the system has checked that both processors are using the same software version the instrument performs the following self checks.

```
Performing the Self Check...           ⬆

Software version:  AAAAAAAAAA

ROM check -  BBBBBBBBB

XRAM check - CCCCCCCCCCCCCCCCCCCCCC

Homing hardware check - DDDDDDDDD


```
Self Check Screen

Software Version:

Displays the version of software runing in processor 1 and in processor 2

ROM checksum test:

The ROM of processor #1 is checked for a predetermined checksum. If the expected checksum value is not found, a "FAIL" message will be shown on the screen.

XRAM test for data corruption:

XRAM memory is checked for a predetermined checksum value. If that value is not found, then a "FAIL" message is displayed on the screen.

Hardware homing test:

The moving table, blotter and readhead are homed by processor #1.

If any of these functions result in an error generation then, a "FAIL" message is displayed on the screen with the appropriate two digit error code.

7-3-2 Ready Screen

Once all of the self checks are completed without failure, the instrument will display the ready screen:

```
Use: AAAAAAAAAAAAAAAA
Place Strip.



 ▣   SEQUENCE #:BBBBB

 ▣   PRINT SETUP

 ▣   SETUP


 ▣   INSTRUMENT TEST
```
Ready Screen

When the instrument is displaying this screen it is ready to detect a test strip and process it as in the customer mode. The difference being that instrument is always in Test Mode #1, which outputs reflectance and decode data for the results.

Set the sequence number:

This displays the sequence number entry screen and allows the sequence number to be set. The present sequence number is displayed with a cursor under the first digit. The number entry keys are active and when the ENTER key is pushed, the number is accepted and returns to the READY screen. A reset key provides means of resetting the sequence number to "00001".

Print Setup:

This prints the current setup for the instrument using the internal thermal printer.

EXERCISE / DIAGNOSTICS TROUBLESHOOTING

Setup:

Selecting this option presents a new screen that displays the functions that can be set.

```
SELECT ITEM TO SPECIFY ITS
OPTION                              ⬆

  ▣  Set the Date AA-BB-CC (M-D-Y)

  ▣  Set the Time DD:EE (24 hr)

  ▣  Clear Memory

  ▣  Printer: FFF

  ▣  Strip Type: GGGGGGGGGGGGGGGGGG
```

Setup sub-menu

Set the Date:

This selection allows the date to be set.

Set the Time:

Selecting this key allows the time to be set.

Clear Memory:

If this selection is chosen, the following display will appear:

```
  Clear all results from
  the CLINITEK memory ?
  Are you sure ?

  ▣  YES


  ▣  NO



  ▣  Reset System Memory
```

Setup sub-menu Clear Memory Screen

Yes:

If this is selected all test results stored in the system are purged.

Reset System Memory:

If selected the fixed memory locations are reset to default values. This must be performed after using the instrument Test Card before installing the customer card.

Printer:

This key toggles the internal printer on or off. The default setting is ON.

Strip Type:

This option allows the user to select what type of reagent strip will be used. MULTISTIX 10 SG is the default strip.

7-3-3 Instrument Tests

The diagnostic tests provided by the Instrument Test Card are grouped in 4 levels or sub menus. Each level of test is displayed as a separate menu on the display

- Level 1 tests all complete subsystem tests.

- Level 2 tests are interface tests.

- Level 3 tests are all related to data collection.

- Level 4 tests operations which are specific to processor 1.

```
  Instrument Tests, Level 1          ⬆

  ▣  INSTRUMENT RELEASE TEST

  ▣  EXERCISE ALL MOTIONS

  ▣  SENSOR STATUS

  ▣  SETUP STRIP CENTERING
                              REBOOT
  ▣  STRIP WALK TEST          SYSTEM ▣

  ▣  LEVEL 2 TESTS
```

Instrument Test Level 1 Screen

7-3-3-1 Instrument Release Test

Equipment Required:

- PC with the following minimum configuration:486 33MHz processor, 8 (16) Megabytes of Memory, 1 free serial port
- Windows 3.11 or 95
- Serial test cable (Null modem DB25 to DB9) (p/n 40453255)
- Instrument Release Test Software (p/n SR00169X)
- Release Test limits file (p/n SR00170X)
- Floating Rail Hold-down (p/n 71647013)
- Hard Standards Test Strip (p/n 95002262)
- Thermal Printer Paper
- Instrument Test Card (p/n SR00081X)
- Refer to the RSL 024E6470 (Recommended Spare Parts List) for the current part numbers for the fixtures

The Instrument Release Test uses a special test strip and a PC running the Release test software to perform a quality check on the operation of the instrument. In this test, data is outputed from the instrument and collected by the PC running the release software. Next, the data is analyzed and compared to predefined limits, and if the results are within the limits, the instrument passes the test. The PC screen will display if the instrument passed or failed.

The Test Hard Standard strip used for the release test has pads in the following positions P4, P9, P10 and P11.

The procedure for performing the Release Test is as follows:

1. With the power off install the Instrument Test Card and connect the CT 500 via the DB25 serial port to the test cable from the PC. Install the Floating Rail Hold-down on the Fixed Table and install the Fixed Table on the instrument

2. Turn the CLINITEK® 500 "ON" and select the Release Test from the menu.

3. Place the test strip onto the reagent load area of the fixed table and push "OK" button.

4. The instrument moves the strip to the first readhead and scans the strip 10 times, doing the normal positioning, calibration, and readhead movement. Only the reflectance results are saved to be outputed.

5. Calibration is performed on the first calibration chip. During the calibration, the reflectances, light counts, and dark counts are stored. Following calibration 29 reflectance reading are taken and stored.

6. The results from the first readhead are stored as sequence number 001.

7. The strip is moved as quickly as possible to the second readhead and steps 3 and 4 are repeated and stored as sequence number 002.

8. The results are available after the strip is read at the second readhead and will be outputed when asked for by a connected computer.

9. If the test is repeated, any results from a previous test are overwritten.

10. The results may be printed also if desired.

NOTE

The full Service Release Procedure is detailed in chapter 12

7-3-3-2 Exercise all motions

When this test is selected, the user will be prompted to select the number of cycles the test will run.

```
┌─────────────────────────────────────┐
│                              ┌───┐   │
│  EXERCISE ALL MOTIONS        │ ⌂ │   │
│                              └───┘   │
│                                      │
│  ┌──┐                                │
│  │◉ │ 10      CYCLES                 │
│  └──┘                                │
│  ┌──┐                                │
│  │◉ │ 500     CYCLES                 │
│  └──┘                                │
│  ┌──┐                                │
│  │◉ │ 8000    CYCLES                 │
│  └──┘                                │
│  ┌──┐                                │
│  │◉ │ 30000   CYCLES                 │
│  └──┘                                │
│                                      │
│       (about 500 cycles/Hr)          │
│                                      │
└─────────────────────────────────────┘
```

Exercise All Motions Screen

All motors and actions are operated as a normal run cycle with the appropriate delays. The number of cycles of operation may be selected. The cycle number being run is displayed and any detected error is displayed. If any errors are generated during the test, the most recent it will be displayed on the screen. The error will be cleared from the screen when the return to ready run key is pushed.

7-3-3-3 Sensor Status

This test displays the current status of all of the mechanical sensors. The normal status of the sensors is shown in the example of the screen, where "AAA, BBB and CCC can have a value of "YES" or "NO".

```
┌─────────────────────────────────────┐
│                              ┌───┐   │
│  SENSOR STATUS               │ ⌂ │   │
│                              └───┘   │
│                                      │
│                                      │
│  TABLE IN PLACE:  AAA                │
│                                      │
│  BLOTTER AT HOME: BBB                │
│                                      │
│  TRANSPORT HOME:  CCC                │
│                                      │
│                                      │
│                                      │
│                                      │
└─────────────────────────────────────┘
```

Sensor Status Screen

The table 7-3-1 below, shows the normal sensor status values when the Fixed and Moving Tables are installed and the instrument is in the "Ready" state.

Sensor	Status
Table In Place	Yes
Push Bar Home	Yes
Transport Home	No

Table 7-3-1

7-3-3-4 Setup Strip Centering

Equipment required:

- Floating Table Hold-down (p/n 71647013)
- Hard Standard Strip (p/n 95002262)

This test performs an automatic strip centering function that positions the strip in the correct location (left to right) under the readheads. Once this test is selected, the screen will display the current centering steps and will prompt the user to place a "hard standard" on the load zone of the fixed table and press the "OK" key. (See screen below)

```
SETUP STRIP CENTERING                ⭡

Steps from sensor to center: AA


◼ OK (Place TEST Strip)
```

Strip Centering Setup Screen

```
 TESTING...

Steps from sensor to center: AA

 BBBBBB
```

Strip Centering Testing Screen

After selecting O.K. the strip moves to one position before the first read station and the readheads move out to the strip mid position. The moving table is then stepped slowly and readings taken on the IR channel to find the 50% reflectance point designated as the edge of the strip. The moving table is then moved 42 steps, to have the strip centered under the readhead. At

some position during the 42-step advancement of the Drive-Mechanism, its home position sensor will change state. The number of steps is counted from the position where the sensor first changes state to the center position. This number is the strip centering value. The strip is then advanced to the second readhead and the procedure is repeated. The Strip centering values from each readhead are checked to be within set limits (4 to 40 steps) and then checked to be within 10 steps of each other. If the strip centering values fail either test, an error condition occurs, the step count is set to "00" and error code #34 is set. The steps from each readhead are then averaged, stored and sent to processor #1 to be stored in permanent memory. Whenever processor #2 is reprogrammed, the "cal factors" message is sent to processor #2, which includes the centering steps as the first 2 digits sent shown as "AA" in the strip centering screen. During operation, the centering steps are used to position the table so that a strip is centered under each of the readheads. To accomplish this the drive mechanism advances the reagent strip a fixed number of motor steps, equal to the strip centering number, past the home position sensor activation point.

NOTE

BBBB can have the value of "PASS" or FAIL"

7-3-3-5 Reboot System

(Key is on the right side of the display on instrument test screen level 1.)

The Reboot System function will send an <ESC> to processor #2 that starts the program at the power ON function. Then processor #1 goes to the initialization program. This allows re-initialization without turning power off and on.

7-3-3-6   Strip Walk Test

Equipment Required:

Normal hold down
10 MULTISTIX-10SG reagent strips

When this test is selected, the instrument prompts the user to prepare to load 10 "Dry"strips, one at a time, on to the load zone of the fixed table. Once the "O.K." key is pressed, the instrument starts the test, as each strip is placed on the load zone of the fixed table the pusher arm is activated and moves the strip to the moving table.

```
SETUP WALK TEST              ⬆

Run 10 Strips...

⬛ OK

```

Strip Walk Setup

```
                             ⬆
                            ABORT
TESTING...




AAAAAAAAAAAAA

```

Strip Walk Testing

As the strips are moved under each readhead, the strip tip is located with respect to each Calibration Bar and stored in memory. After all ten strips have had the tip locations determined by both readheads the data is analyzed. A print out of the data and test results is printed out on the internal printer (see figure 7-3-1).

```
Strip Position Data
RH1  4 5 4 5 4 4 4 4 4 4
RH2  4 4 4 4 4 4 4 4 4 4
RH1  Ave. = 4.2
RH2  Ave. = 4.0
Strip Walk Test = B
```

Printed Strip Walk Test Report
Figure 7-3-1

The first line of data printed is location of each of the ten strips read under Readhead 1 (RH1). The second line of data printed is location of each of the ten strips read under Readhead 2 (RH2). These measurements (in motor steps) can range between "0" and "8", with "4" being ideal.

A number lower than "4" indicates that the tip of the strip is closer to the calibration bar.

A number greater than "4" indicates that the tip of the strip is further away from the calibration bar.

The next two lines are the average position values for the ten strip readings taken under each readhead, "RH1 Ave." and "RH2 Ave."

The last line which is printed "Strip Walk Test = X " where "X" can be equal to one of three values, **A, B** or **C.** These values represent different sets of criteria, which the assembly passes

> **C** = A strip position of "0" or "8" was detected at either readhead
>
> **B** = A strip position of "2" or "6" occurred six or more times at either read head,
> **or**
> the average for either readhead was less than 3 or greater than 5.5,
> **or**
> a strip[position of "1" or "7" was detected at either read head.
>
> **A** = None of the Above

Different sets of testing criteria are used for "New" Drive housing assemblies (Assemblies with less than 8000 cycles) and a "Used" Drive housing Assembly (8000 or more cycles).

"New" Drive Housing assemblies must report

"Strip Walk Test = A".

If "B" or "C" is reported with a "New" assembly it
fails the test.

"Used" Drive housing assemblies must report:

"Strip Walk Test = A or B".

The criteria for the "Used" assembly makes
allowances for "normal " parts wear.

Any Drive Housing Assembly which reports:

"Strip Walk T= C"

 Fails the test.

NOTE

***All new instruments have passed a burn in test in
which the drive housing has cycled 8000 times.***

In case of a system failing this test, the Drive
Housing assembly will require
that the horizontal plate be realigned
(See section 8-3), or the Drive Housing replaced
(See section 9-17)

7-3-4 Level 2 Tests

The tests at this level exercise the I/O interfaces with all subassemblies that require bi-directional communication.

```
Instrument Tests, Level 2          ⏏

 ⬛ TEST SERIAL PORTS

 ⬛ TEST PRINTERS

 ⬛ TEST TOUCH SCREEN

 ⬛ TEST STRIP DETECTOR

 ⬛ TEST DISPLAY

 ⬛ LEVEL 3 TESTS
```

Instrument Tests, Level 2 screen

7-3-4-1   Test Serial Ports

Selecting this test will bring up the following screen that allows the selection of which serial port to test.

```
TEST SERIAL PORTS                  ⏏

(Install loop-back connectors)

 ⬛ COMPUTER PORT


 ⬛ BAR CODE READER PORT


 ⬛ AUXILIARY PORT
```

Test Serial Ports

Each of the three serial ports; computer port, bar code port, and the auxiliary port may be tested using a "loop-back" connector. Refer to the RSL for the part numbers for the appropriate "loop-back connector.

A test message is sent and the received message displayed. The first and last characters are checked for correspondence.

```
AAAAAAAAAAAA


BBBBBBBB



SENDING: 0123456789 ABCDEFGHIJK


RECEIVING: CCCCCCCCCCCCCCCCCCCCC
```

Serial Ports Testing

7-3-4-2   Test Printers

Selection of this test allows for testing communications with both the internal and external printer.

```
TEST PRINTERS                      ⏏



 ⬛ INSTRUMENT PRINTER TEST



 ⬛ EXTERNAL PRINTER TEST
```

Test Printers

Selecting the Instrument Printer test sends a test message to the instrument printer. The message is a combination of ASCII characters that test all of the pixels of the printer.

The External PrinterTest is tested by sending the same ASCII message but requires connecting a printer. An example of the print out is below.

```
1. 0123456789)
2. CAPS small letters. ▲▼
```

Printer test output

7-3-4-3   Test Touch Screen

The touch screen test routine displays a test screen and pushing it at any location displays a marker "+". The line and column sensed is displayed along with the A-D readings from that location.

```
     PUSH ANYPLACE TO TEST TOUCH SCREEN
AAAA BBBB
CCCCC DDDDD




                        ⊡ ERASE   ⊡ EXIT
```

Touch Screen Test Screen

AAAA: Will display "C=" the column that was touched on the screen.

BBBB: Will display "R=" the row that was touched on the screen.

CCCC: Will display "X=" the X-coordinate that was touched on the screen

DDDD: Will display "Y=" the Y-coordinate that was touched on the screen

Erase: Clears all +'s from the screen and deletes the coordinates in the upper left corner of the screen.
Exit: Returns to the Instrument Test Level 2 screen

7-3-4-4   Test Strip Detector

```
                                      ⬆
TEST STRIP DETECTOR


PLACE STRIP

⊡ PRINT DETECTOR SETUP VALUES


⊡ STRIP VERIFY TEST
```

Test Strip Detector Screen

Print Detector up values

If the "Print detector setup values" is selected the values of the current detector setup are printed on the instrument printer. (See example below) The allowable range for the setup values are 10 to 254.

```
 Detector setup values
067 046 055 055

049 055 058 078 99
```

Strip Verify Test

This test will allow checking to determine if the strip detector will sense the presence of a strip in the load zone. Whenever the detector is tripped the instrument will respond with a "beep"

7-3-4-5   Test Display

When this test is selected the screen will display "ALL PIXELS WILL BE DISPLAYED " for 2 seconds, then all of the pixels on the display will be turned on for 5 seconds then turned off for 5 seconds. After this has completed it will return to the Instrument Test Level 2 screen.

7-3-5 Level 3 Tests

This group of tests is designed for testing the illumination, pre-amp and A/D subsystems of the instrument.

```
Instrument Tests, Level 3            ⬆

 ON        OFF     LAMP AAA


 READ A-D COUNTS

 TEST READHEADS

 REFLECTANCE TEST

 LEVEL 4 TESTS
```

Instrument Tests, Level 3 screen

AAA: Displays the current lamp status ON or OFF

7-3-5-1   Lamp ON/Off

This option allows the lamps to be toggled on or off as desired. It is useful when used in conjunction with other tests to determine specific information about the readhead Pre-amps and A/D PCB.

7-3-5-2   Read A-D Counts

This shows the A-D converter RAW counts read from viewing whatever the readhead are positioned over. All eight channels of A-D readings are printed out on the internal printer and sent to the computer port. (An example of the printout is located at the top of the next column)

```
      CHANNEL A-D COUNTS
      IR  RED GREEN BLUE
NOMINAL
RD1 0200 0185 0200 0193
RD2 0205 0188 0188 0200
4 STEPS IN
RD1 0200 0186 0200 0200
RD2 0205 0187 0190 0200
4 STEPS OUT
RD1 0200 0186 0202 0200
RD2 0205 0188 0189 0203
```

Sample Read A/D print out

The limits for the A/D counts are listed below:

Readhead-channel	Lamp on	Lamp off
1-IR	800-2046	1-400
1-RED	800-2046	1-400
1-GREEN	800-2046	1-400
1-BLUE	800-2046	1-400
2-IR	800-2046	1-400
2-RED	800-2046	1-400
2-GREEN	800-2046	1-400
2-BLUE	800-2046	1-400

A/D Limits

7-3-5-3   Test Readheads

When this test is selected, the readheads are homed on the cal chip using readhead #1. Readings, as A-D converter counts, for the cal chip and the dark values for all 8 channels are printed. Additionally, the readhead #2 cal chip edge correction value is also measured and printed. This indicates the number of read positions (0.01716") that readhead #2 is in (-) or out (+) from readhead #1. An example of the print out from the internal printer is below.

```
     READHEAD TEST
      IR   RED GREEN BLUE
CA1 1379 1254 1209 1245
DK1 0200 0185 0202 0200
CA2 1482 1278 1226 1271
DK2 0203 0187 0192 0201

RH2 CAL EDGE CORR. = -1
```

**Sample Test Readheads
Printout**

The limit for the RH2 Calibration Edge Correction is +/- 3 (it is highly desirable to have this reading +/- 1). If the value is outside of the +/- 3 range a General Error 30 will be generated.

The acceptable range for CA1 and CA2 is 600 to 1846.

The acceptable range for DK1 and DK2 is 1 to 400.

7-3-5-4   Reflectance Test

(Displays the "Place Test Strip" screen)

A hard standards strip is placed at the load station of the fixed table and "OK" pushed to start the operation. The strip is moved to the first readhead, scanned and then moved to the second readhead, scanned and moved to the waste station. The reflectance values for all 11 pad positions from each readhead (a total of 88 reflectance values) are then available for printout or output to the PC port. At the completion of the test the user may print the test data from either or both readheads (See example of the printout). The user also has the option of repeating the test.

```
#00001 9707161505
 3000 80
     IR   RED GREEN BLUE
A1  0113 0057 0089 0107
A2  0113 0064 0097 0144
A3  0038 0028 0097 0097
A4  0125 0068 0106 0107
A5  0115 0057 0101 0107
A6  0113 0057 0093 0090
A7  0113 0057 0089 0097
A8  0115 0057 0097 0114
A9  0110 0057 0093 0124
A10 0066 0036 0114 0084
A11 0113 0057 0080 0090
```

Sample Readhead 1 Data

```
REFLECTANCE TEST
  Both read-heads, 11 positions
  (A11/B11 at tip)


 OK  (Place TEST Strip)
```

Reflectance Test Start Screen

```
REFLECTANCE TEST
  Both read-heads, 11 positions
  (A11/B11 at tip)

 OK (Place TEST Strip)


 PRINT READHEAD #1 DATA

 PRINT READHEAD #2 DATA
```

Reflectance Test Completed Screen

```
#00001 9707161505
 3000 80
     IR   RED GREEN BLUE
B1  0113 0057 0089 0107
B2  0113 0064 0097 0144
B3  0038 0028 0097 0097
B4  0125 0068 0106 0107
B5  0115 0057 0101 0107
B6  0113 0057 0093 0090
B7  0113 0057 0089 0097
B8  0115 0057 0097 0114
B9  0110 0057 0093 0124
B10 0066 0036 0114 0084
B11 0113 0057 0080 0090
```

Sample Readhead 2 Data

7-3-6 Level 4 Tests

The tests grouped in this level confirm proper operation of the control circuits for Readheads, Moving table and the pusher bar. Additionally two tests are available for determining if data is transferring between the two processors correctly.

```
Instrument Tests, Level 4            ⬆

▣ CYCLE READHEADS

▣ CYCLE TABLE

▣ CYCLE PUSH BAR

▣ READ STRIP, DUMP DATA

▣ PRINT TRANSFERRED DATA

▣ GENERATE LEU CORR. FACTOR
```

Instrument Tests, Level 4 screen

7-3-6-1   Cycle Readheads

Move the readhead mechanism one full cycle.

7-3-6-2   Cycle Table

Advance the moving table one complete cycle.

7-3-6-3   Cycle Pusher arm

Move the pusher arm one complete cycle.

Note: Any errors generated in the above tests will be displayed on the screen.

7-3-6-4   Read Strip, Dump Data

This test provides a means of viewing the raw data without being routed through processor #2, thus isolating data errors.

A hard standards strip is placed at the load station of the fixed table and then "OK" pushed to start the operation. The strip is moved to the first readhead and scanned. All data, as A-D counts are transferred to processor #1 which echoes the data to the RS-232 port. There is no storage or handshaking involved. The strip is then moved to the second readhead and the process is repeated. The strip is then moved to the waste bin.

```
READ STRIP, DUMP DATA            ⬆

▣ OK  (Place TEST Strip)
```

Read Strip Dump Data Screen

7-3-6-5   Print Transferred Data

Allows printing of whatever data message was last sent to processor #1 from processor #2 on the instrument printer see example below.

```
00
#00003 9707151307 000044
6608 2508 0707 5608 2205
0856 0503 0612 0489 0571
0665 0688 0707 0609 1063
0636 0658 0623 0519 0980
0804 0825 0753 0609 1963
0826 0830 0722 0573 1144
0844 0761 0660 0534 0842
0838 0761 0660 0534 0842
0838 0755 0614 0431 0733
0868 0820 0683 0608 0834
0426 0388 0370 0350 0292
0842 0814 0691 0590 1000
0830 0819 0722 0648 0871
9D
```

Transferred Data Printout

7-3-6-6   Leukocyte Correction Factor Generation

Equipment Required

- Instrument Test Card (version 1.03 / 1.03 or higher)
- CT500 Calibration Solution (95002503)
- Multistix 10 SG reagent strips (10 each)
- Urinetek tubes of equivalent
- Test Tube Holder (optional)
- Paper Towel

To reduce variability between instruments, a "Correction Factor" was added to the Leukocyte algorithm. This factor accounts for minor variations of Reagent Strip alignment and Readhead position during data collection that exists between systems. This Correction Factor can only be set using the Instrument Test Card. New instruments will have this factor set during manufacturing; existing instruments (with 1.04/1.03 user software or above) should have

this Factor set during normal service release testing. Existing instruments in the field will not necessarily need this procedure performed but may if required to satisfy customer expectations for LEU performance

This test takes reading from a Multistix 10 SG reagent strip which has been dipped into "CLINITEK 500 Calibration Solution" (part number 95002503). Ten strips are required to be processed by the instrument during this test. The instrument process the data collected and results are printed, displayed on the screen and stored in the instrument SRAM for permanent use by the instrument.

Scroll through the menu options until you reach the "Instrument Tests, Level 4" menu (see below). Select the "Generate LEU Corr Factor" menu option.
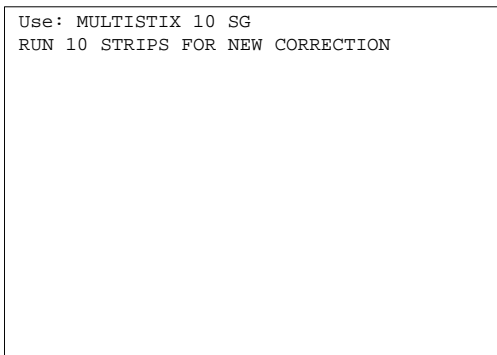
```
Instrument Tests, Level 4            ⭡

 ▣  CYCLE READHEADS

 ▣  CYCLE TABLE

 ▣  CYCLE PUSH BAR

 ▣  READ STRIP, DUMP DATA

 ▣  PRINT TRANSFERRED DATA

 ▣  GENERATE LEU CORR. FACTOR
```

The first screen displayed in the LEU Correction Factor test is shown below.

```
LEU CORRECTION FACTOR: AA            ⭡

 ▣  GENERATE LEU CORR. FACTOR
```

The variable "AA" indicates the current LEU correction factor stored for the instrument. The correction factor can have value from –99 to +99.
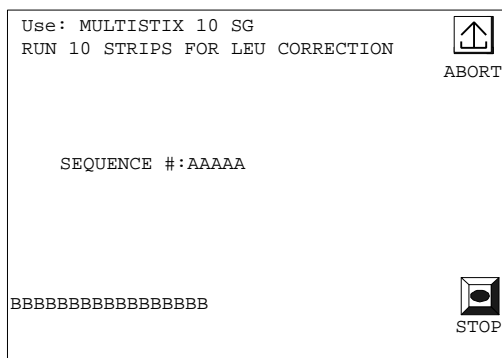
If the Instrument has not previously had a LEU correction Factor generated the value of "AA" =00 and no sign (+ / -) will be shown.

To set a new correction factor press the key "Generate LEU Corr. Factor", which will then display the following screen.

```
Use: MULTISTIX 10 SG
RUN 10 STRIPS FOR NEW CORRECTION
```

When the above screen is displayed, the instrument is ready to start having strips placed upon the load zone of the instrument.

Immediately place strip on instrument fixed table. The strip will be detected and pusher bar will move strip to the readhead areas. After the first strip has been detected, the display will change as shown below.

```
Use: MULTISTIX 10 SG
RUN 10 STRIPS FOR LEU CORRECTION
                                    ABORT

    SEQUENCE #:AAAAA



BBBBBBBBBBBBBBBBBB
                                    STOP
```

Note

The variable "AAAA" is the sequence number of the strip that is being processed.
The Variable "BBBBBB" is an Error message if an error condition is detected and is report as a normal CLINITEK 500 error code.

Once started, you need to dip another strip and place on the table for every 7 second cycle until all 10 strips have been run. Ten (10) strips must be run for the instrument to be normalized.

Note

Once started, all 10 strips must be run without missing a 7-second cycle. If you miss a cycle, the test will report an error and you will need to run the test again.

All 10 strips can be dipped in the same tube of leukocyte negative solution. However, a tube of leukocyte solution is good for only 10 strips and must be discarded after each complete test is run.

```
LEU Correction Factor

    AVERAGE:   AAA

    MAXIMUM:   BBB

    MINIMUM:   CCC

    RANGE:     DD
```

Once all ten strips have been processed, the results are displayed on the screen as shown above. A printout of the data sets and the minimum, maximum, range, and average decode results will automatically be printed after CT500 normalization is complete.

An instrument passes the test if the range value for the test is less than or equal to 34.

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7-4 Detailed Troubleshooting and Testing

7-4-0 Introduction

The following section describes how to troubleshoot key subassemblies of the CLINITEK 500 instrument to determine if they are operating properly.

Caution

Except where otherwise specifically requested, always power off and unplug the instrument when servicing.

When ever working on the instrument with the cover off the standard Electro Static Discharge (ESD) precautions should be followed.

When ever handling the Preamp PCBs, A/D PCB or Lamps clean white cotton gloves must be worn.

7-4-1 Pre-amp PCB

Equipment required:

Instrument Test Card SR00081C
Digital volt meter
Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display, using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing.

4. Manually position the readhead over the calibration chip.

5. Using the lamp ON / OFF test in the Instrument Test Card (Refer to section 7-3-5-1) turn the lamp ON.

Figure 7-4-1

6. Use a DVM to measure the outputs of the four channels of the pre-amp. A convenient location to measure these are at connector P1 and P2 on the A/D PCB (Refer to figure 7-4-1). Place the ground lead on the power supply chassis and measure the output of pins 2,3,4,and 5. Typical readings are 1 to 4 volts with the lamp on and about 0 with the lamp off refer to table 7-1 below.

Table 7-1

	GRN	IR	RED	BLU	Lamp Status
Pin	2	3	4	5	
Vdc	1-4	1-4	1-4	1-4	ON
mVdc	0	0	0	0	OFF

7-4-2 A/D PCB

The A/D PCB provides all of the reference voltages to the pre-amp PCB. Use the following procedure to verify that the correct voltages are being provided to the Pre-amp PCBs and lamps. If any of the voltages are not present, the A/D PCB should be replaced.

Equipment required:

Instrument Test Card SR000810
Digital volt meter
Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing.

4. Manually position the readhead over the calibration chip.

5. Using the lamp ON / OFF test in the Instrument Test Card (Refer to section 7-3-5-1) turn the lamp ON.

6. Measure the lamp voltage between pins 1 and 2 on both connector P4 and P5 (Refer to figure 7-4-1). The unloaded voltage should be between +5.8 VDC and +6.24 VDC.

7. Reconnect the lamps and measure the loaded voltage. It should be between +5.8 VDC and +6.24 VDC.

8. Measure the voltages at pin 7 of connectors P1 and P2 (Refer to figure 7-4-1), voltages should be 4.95 VDC to 5.05 VDC.

9. Measure the voltages at pin 8 of connectors P1 and P2 (Refer to figure 7-4-1), voltages should be -5.2 VDC to –4.84 VDC.

10. The input voltage measured on P3: pin 4 should be -12 VDC and pins 9 & 10 should be +12 VDC.

7-4-3 Mother PCB

7-4-3-1   Power input

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display, using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing 1

4. Measure the output voltage from the power supply at connector P12 on the mother PCB (Refer to figures 8-1). Place the NEG lead of a DVM on pin 3 or 4 (GND) and the POS. lead on the following pins. The voltage should be within 10% of the listed voltages below.

    | Pin 1 &2 | +5 VDC |
    | Pin 6 | -12 VDC |
    | Pin 9 | +12 VDC |

7-4-3-2   Power to the Strip Detector

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing 1

4. Power to the Strip Detector can be checked on the back of the strip detector PCB (Refer to figure 7-4-2). Place the NEG lead of the DVM on Pin 1,4,or 5 which are GND (The meter can also be connected to the power supply chassis for the DC ground).

5. Connect the POS. lead of the DVM to Pin 3 of the cable, the voltage should be +12 VDC. Connecting the POS. lead of the DVM to Pin 2 of connector 8 the voltage should be -12 VDC.

7-4-3-3   Power to the Printer

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647014

Procedure

1. Disconnect the line cord from the power entry module and remove the upper case (Refer to section 9-8).

2. Reconnect the line cord to the power entry module and turn the power switch ON.

3. Connector P7 on the Mother PCB provides the power to the printer. Remove the cable from the connector.

4. Measure the voltages present at the connector: connect the NEG lead of the DVM to Pin3 (GND) and the POS. lead to Pin 1. The voltage should be +5.0 VDC. Move the POS. lead to Pin 2 the voltage should also be +5.0 VDC. If the voltages are not present check to see if the power supply is operating (Refer to section7-4-3-1).

Figure 7-4-2

7-4-3-4   Stepper Motor Drive Circuits

The following procedure will determine if the stepper motor drive circuits are functioning correctly.

Equipment required:

- Oscilloscope
- Instrument Test Card SR00081C
- Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display, using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing 1

4. Use the Instrument Test Card to excise all motor functions of the instrument (section 7-3-3-2). Measure the output of IC 5, 6 or 7 at pins 8, 1, 6, and 3 while the appropriate stepper motor is operating. The waveforms observed should be a square wave.

Note

The waveform will exhibit some inductive noise as the winding is turned off.

---

5. To determine if the stepper motor driver chip if functioning properly, Measure the input signal at Pin 11 (see table7-4-2 for duration times).

Table 7-4-2

IC Number	Pin Number	Pulse Length
U5	11	3 msec
U6	11	3 msec
U7 (travel out)	11	2 msec
U7 (travel in)	11	1 msec

If the input is present but any of the output wave forms are missing or not of the proper shape (should be square-wave), replace the Mother PCB

If there is no input signal then the problem lies on the Processor PCB.

7-4-3-5   Trouble shooting the RS232 ports

Equipment required

- Instrument Test Card SR00081C
- RJ45 RS232 Loop Back connector 71647006
- DB-25 RS232 Loop Back connector 71520102

Procedure

1. Install the Instrument Test Card and use the test software (Refer to section 7 3-4-1) to check to see if the ports work with the loop back connector.

2. Repeat the loop back test for each port. If the test fails replace the motherboard and rerun the test.

If the test fails for a second time the problem lies on the Processor PCB and it will require replacement

7-4-3-6 Bar code reader communications

Equipment required

- Instrument Test Card SR00081C
- DB-25 RS232 Loop Back connector 71520102
- Digital Volt meter
- Bar code port Loop-Back test fixture 71647007

Procedure

1. Install the Instrument Test Card and select the serial port tests (Refer to section 7-3-4-1)

2. Using the Bar-code port test fixture, measure the voltage at connector J5. The voltage between pin 6 and ground, pin 1 or 3, should be 5 VDC. The voltage between pin 7 and pins 1 or 3 should be +12 VDC.

3. If these voltages are not present the Auto Reset Fuses are damaged. Replace the Mother PCB

4. Use the Bar code test port fixture and enter the bar code reader communications test. (Refer to section 7-3-4-1) If the test passes the problem is with the bar code reader, if it fails replace the motherboard and retest.

5. If the test fails a second time, replace the Main Processor PCB.

7-4-4 Sensor Tests

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing.

4. Turn the instrument on. Select the first level of instrument tests and select Sensor Status (Refer to section 7-3-3-3).

5. Interrupt each of the sensors and observe that the status changes. If the status fails to change replace the sensor and perform the test a second time.

6. If the sensor test fails a second time, the problem may lie in the Mother PCB or with the Main PCB.

7-4-5 Display Testing

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647014

Procedure

1. Remove the upper case (Refer to section 9-8).

2. Reconnect the display, using the Display Test Fixture.

3. Install the Instrument Test Card and reconnect the power cord to allow operation during servicing. Next select display test display (Refer to section 7-3-3-5). If the display fails this test, proceed to the next step.

4. Verify that the display assembly is receiving power. Remove the Display bezel assembly from the instrument leaving the cable connected to the Main Processor PCB.

5. Using a volt meter check for voltage being present on the display interface PCB while the instrument power is on.   top of chapter

6. Connect the Negative lead of the volt meter to connector P2 pin 20 and connect the positive lead to pins 5, 16 and 17. The voltage measured on each of these pins should be +5 VDC.

7. Connect the positive lead to Pin 1,its voltage should be +12 VDC.

8. If the voltages are not present on the display, check the connector on the Main Processor PCB for the voltages.

9. If the voltage is presenton the main processor PCB then the display assembly is defective and requires replacement.

7-4-6 Main Processor PCB

Equipment required:

- Instrument Test Card SR00081C
- Digital volt meter or equivalent
- Display service test fixture 71647013
- Known good display assembly

Procedure

In the process of testing most of the instrument functions, a determination can be made if the Main Processor PCB board is operating properly.

Since user interface functions are controlled by processor 1 and motor control by the processor 2 ,it is possible to isolate problems to either the Single inline Memory Module (SIMM) which contains processor 1 and its associated support circuitry, or the Main PCB which processor 2 is located on.

1. If on power up (with the program card removed), there is no motor movement from; Readhead, moving table or blotter the SIMM module is possibly defective and requires replacement. (Refer to section 9-12-1)

2. If when the unit is turn on the display is blank, the power supply should be checked for proper output voltage (Refer to section 7-4-3-1). Additionally the cables going to the display should be checked to see if they are seated properly, then the voltage to the display checked (Refer to section 7-4-5).

3. If all the voltages are correct, use a known good display to verify that the problem is not the display. If a known good display fails to operate then the Main Processor PCB should be replaced (Refer to section 9-12).

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CHAPTER EIGHT-ALIGNMENTS / ADJUSTMENTS   *Return*

8-0   Introduction

This section of the manual provides detailed information required for making necessary alignments and adjustments during the ordinary course of repair on the CLINITEK® 500 Urine Chemistry Analyzer. It also describes what special fixtures are required and how to use them.

Caution

Except where otherwise specifically requested, always power off and unplug the instrument when servicing.

Whenever working on the instrument with the cover off the standard Electrostatic Discharge (ESD) precautions should be followed.

Whenever handling the Preamp PCBs, A/D PCB or Lamps clean white cotton gloves must be worn.

8-1   Voltage adjustments

Tools:
- #2 Philips head screwdriver
- Potentiometer adjustment tool or small standard blade screwdriver
- Voltmeter
- Display Test Stand Fixture (p/n 71647014)

Procedure

1. Only the 5-volt power supply output is adjustable. Potentiometer VR1 is used to adjust this voltage. Remove the upper case of the instrument, section 9-8.

2. Install the Display Test Stand Fixture (PN 71647014) which holds the Display assembly and reconnect the Display Assembly to the Main PCB.

3. Measure the output voltage of supply V1. Terminal 1 of TB2 which is the positive output and terminal 4 of TB2 which is DC Ground (Refer to figure 8-1).

4. The nominal output voltage should be +5 volts DC (Range from 4.75 VDC to 5.25 VDC) If the voltage is not with in this range, locate potentiometer V1 (refer to figure 8-1) and adjust the voltage while monitoring it on the meter.   top of chapter

Figure 8-1

Figure 8-2

8-2   Readhead Alignment

<u>Tools:</u>
- Readhead Alignment and Belt tensioner Fixture (p/n 71647017)
- #2 Philips head screwdriver
- 1.5 mm hex wrench
- Torque driver with1.5 mm hex bit and #2 Philips bit
- Instrument Test Card
- Fixed Table
- Moving Table
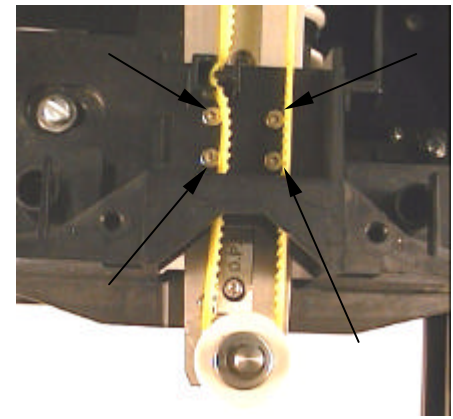- Display Test Stand Fixture (p/n71647014)
- Cotton Gloves

Caution

Whenever working on the instrument with the cover off the standard ElectroStatic Discharge (ESD) percautions should be followed.

Whenever handling the the Preamp PCBs, A/D PCB or Lamps clean white cotton gloves must be worn.

Procedure

1. Remove the upper case (See section 9-7) and reinstall the display assembly test stand.

2. Remove the Preamp PCBs and A/D PCB assembly from the readhead carrier assembly (section 9-16-).

3. The readhead carrier needs to be manually moved towards the front of the instrument two to three inches (5 cm to 7.5 cm)

4. Install the Readhead fixture as shown in Figure 8-3.

5. Loosen the four hex screws shown in figure 8-2 and move the readhead carrier against the fixture. Be sure that the readhead is flush against the fixture.

6. Tighten the four mounting screws in the readhead carrier. Ttorque to 5 inch pounds.

7. Loosen the readhead drive motor mounting screws.

8. Apply pressure to the motor until the belt tension indicator Is centered on the "set-line"

9. Retighten the motor mounting screws to 12-inch lbs. of torque.

10. Manually move the readhead carrier away from the alignment fixture and then remove the fixture from the transport assembly.

11. Reinstall the Preamps and A/D PCBs to the readhead carrier. (Refer to section 9-16)

12. Install the Moving and Fixed Tables on the instrument, sections 9-6 and 9-5.

13. Insert the Instrument Test Card into the instrument and turn the power ON. Wait for the self-checks to complete. Select the test option for testing the readhead (refer to section 7-3-5-3). The instrument will home on the Cal chip using readhead 1 and readhead 2. The cal chip correction factor is printed. Check that the correction factor is with in the Limit *(+3 steps to –3 steps).*

NOTE

It is desirable to have the Correction Factor between +1 and –1.

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14. If the test fails, inspect the readhead and Preamps for proper assembly, try a different Fixed Table and check the table guides are not loose or broken.

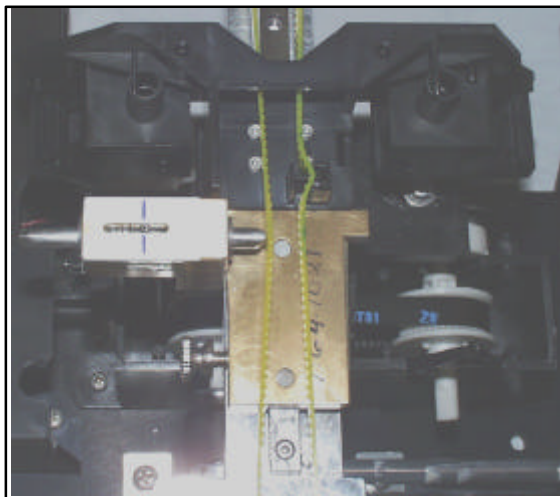15. Re-assemble the instrument as required to complete servicing.   top of chapter
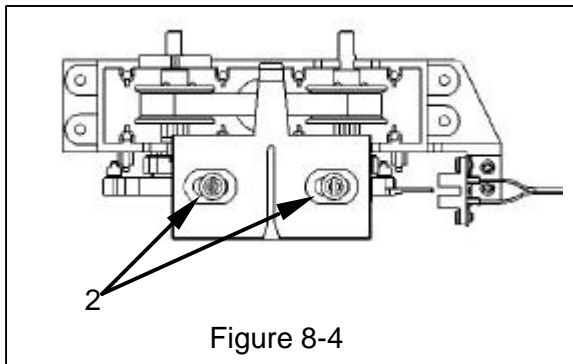

Figure 8-3

8-3   Horizontal plate adjustment

Tools:
- Moving table alignment fixture 71647012
- #2 Phillips head screwdriver
- Standard blade screwdriver
- Instrument Test Card
- Test Strip

Procedure

1. Remove the upper case assembly from the instrument. (Section 9-7) ad the Fixed and Moving Tables (refer to sections 9-5 and 9-6).

2. Loosen the two screws in the horizontal plate. (See figure 8-4)

3. Install the Moving Table alignment fixture on the horizontal plate on to the drive housing.

4. Install the Fixed Table portion of the alignment fixture.

Figure 8-4

5. Rotate the Mechanism so that the fingers of the Moving Table are in the "UP" position. To do this, use a pair of pliers to grasp the motor coupling and rotate it.

6. With the finger s of Moving Table in the "UP" position, center them in the slots of the Fixed Table portion of the alignment fixture, tighten the two screws in the horizontal plate of the drive housing. (5 inch pounds) Ensure that the horizontal plate is fully to the right, with the chamfer against the locating tab (not riding up on it).

7. Rotate he Mechanism so that the fingers of the Moving Table are "Down" and remove the alignment fixtures.

8. Reassemble the instrument and perform the "Set up Strip Centering" test and "Strip Walk Test" (refer to sections 7-3-3-4 & 7-3-3-6). If either test, fails repeat the alignment procedure.   top of chapter

8-4   Printer Adjustments

Tools:
- Instrument Test Card
- Small standard blade screwdriver
- Cotton tip applicators or equivalent
- Isopropyl Alcohol

Procedure

8-4-1 Cleaning the print mechanism

1. Remove the printer assembly from the instrument (section 9-4).

2. Manually advance the print heads to the center of its travel using the thumb wheel gear on the right side

3. Clean the rails that the print-head rides upon using cotton tip applicators moistened with isopropyl alcohol. (*The ends of the rails tend to collect a build up of dirt that after time may affect the operation of the printer*).

8-4-2 Cleaning the printer platen

1. Use alcohol and a cotton applicator to clean the surface of the platen and to remove any build up of dirt. or wax   top of chapter

Note
If the platen gets excessively dirty, it can influence the quality of the printing by creating areas of light printing on the paper

8-5   Sensor adjustments

The optical sensors, location and position, have been designed to eliminate the need for most their physical adjustments. However, It has been found that to insure proper performance the sensors do have optimal positions:

Table in place sensor; positioned fully forward

Crank Arm sensor; positioned fully down

Moving Table sensor; positioned fully left and table flag centered in slot.   top of chapter

8-6   Pusher Bar Slide Lubrication

Tools
- #1 Philips screw driver
- Lubricant (p/n 50996008)
- Instrument Test Card

Procedure

1. Remove the upper case assembly (Refer to section 9-7).

2. Remove the Push Bar Shaft by removing the Phillips head screw that secures it to the Motor Casting (see figure 8-6). Once the screw is loose, remove the Push Bar Shaft. (*Refer to section 9-18 for more detailed instruction for disassembly and reassemble of the Push Bar Shaft and Crank arm.*)

3. Clean the dirt and old grease off the shaft and Slide Arm.

4. Reassemble the Slide Arm and shaft to the Baseplate Assembly.

5. Apply a thin film of grease to the shaft using a cotton tip applicator or fingertip. Move the Slide Arm to allow grease to be applied to both ends of the left and right sides of the shaft.

6. Reassemble the instrument (Refer to section 9-7).

7. Install the instrument Test Card, select the exercise All Motions Test (Refer to section 7-3-3-2), and Cycle the Motions 10 times to work the grease in.   top of chapter
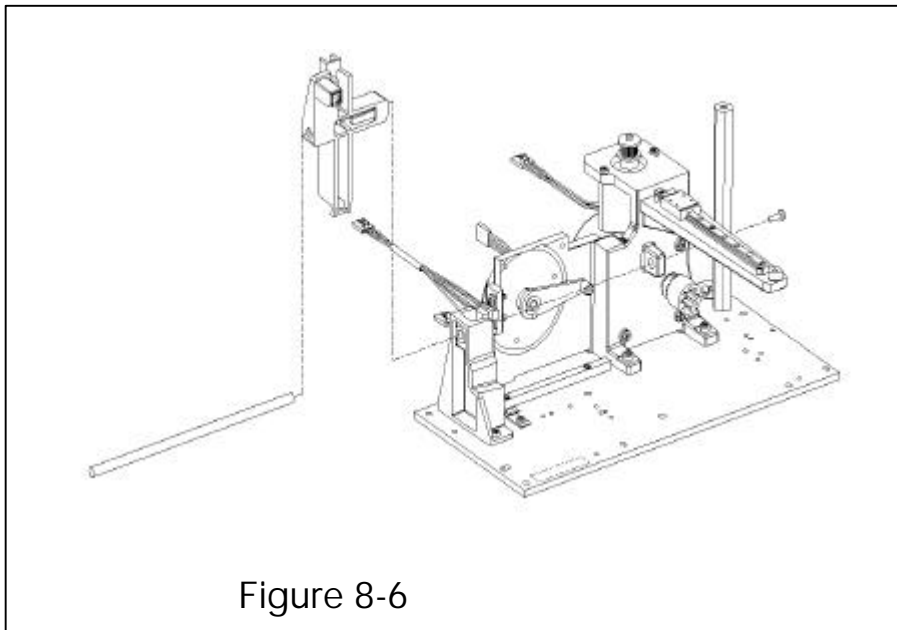

Figure 8-6

CHAPTER NINE – REPAIR / REPLACEMENT   *Return*

9-0   Introduction

This section contains instructions for servicing the
CLINITEK® 500 Urine Chemistry Analyzer.
Special reassemble precautions are noted.

Always perform the preventive maintenance
procedures in Section Five when servicing this
instrument. The "Service Release Protocol" from
chapter 12 must be performed prior to the
instrument return to the customer for use.

Caution
Except where otherwise specifically requested always power off and unplug the instrument when servicing. **Whenever working on the instrument with the cover off the standard Electro Static Discharge (ESD) precautions should be followed.** **Whenever handling the Pre-amp PCBs, A/D PCB or Lamps clean white cotton gloves must be worn.**

9-1 Push Bar Dis/Assembly
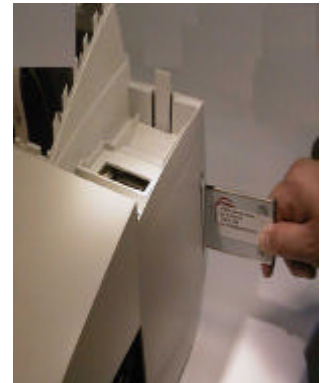
Tools required:
- none

Disassembly

1. The Push Bar is located on the left front side, above the Fixed Table mounted horizontally.

2. Grip the Push Bar and pull up and out to disengage it from the Push Arm Slide.

Assembly

3. While holding onto the finger grip end of the Push Arm, slide the tab end into the Push Bar Slide hole.   top of chapter

9-2 PCMCIA Program Card

Caution

Do not remove or install the PCMCIA card with the power on. This will result in loss of data in the SRAM

Tools required:
- none

Disassembly

1. The PCMCIA Program Card is located on the right side of the instrument toward the rear.

2. Above the edge of the Program Card is a black rectangular button. Push inward on the button and the Program Card will slide out ¼ inch (.8 cm).

3. Grip the Program Card by edge and pull outward

Assembly

4. Hold the Program Card so that the arrow is pointing towards the instrument and the words "Insert This Way" are faceing the front of the instrument.

5. Insert the Program Card into the slot on the right side of the instrument, toward the rear.

6. Push the Program Card inward until the black rectangular button pops out.   top of chapter
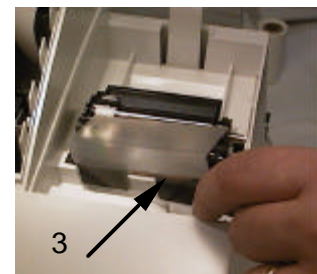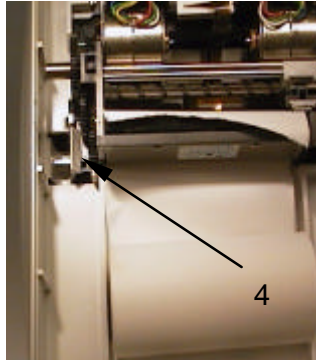
9-3 Printer Module Dis/Assembly

Tools required:

Disassembly

1. Remove the printer cover portion of the Upper Case by pushing in on the center tab at the rear of the printer cover and lifting the cover upward.

2. Remove the printer paper by pulling out of backside of the printer.
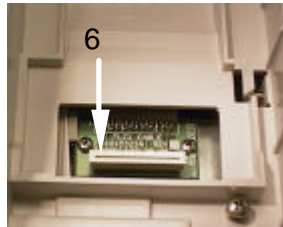
3. Remove the printer shield.

4. Push the printer-locking tab on the right side of the Printer Module. Pull the rear of the Printer Module upward.

4

Caution

The printer flex cable is plugged-in under the Printer Module.

---

5. With the rear of the Printer Module lifted up, the Printer Module will now disengage from the front locating tabs with a backward/upward movement.

6. The printer flex cable goes to a Zero Insertion Force (ZIF) connector. Pull upward on the outer cover to unlock the printer flex cable from the ZIF connector.

6

7. Once the ZIF is unlocked, carefully pull the metallic contacts of the Printer Module out of the connector.

Assembly

8. Pulling up the locking ZIF connector permits the insertion of the printer cable.

9. Carefully insert the printer flex cable into the connector.

Note

The siliver side of the flex cable contacts should be facing towards the front of instrument

When the cable is fully seated in the connector, none of the silver contacts will be exposed.

---

10. When the contacts are properly engaged, push down on the ZIF connector to secure the cable in place.

11. Insert the front locating tabs of the Printer Module under the securing tabs of the Upper Case.

12. Push the rear of the Printer Module down and ensure that it locks into position with the securing tab at the back right hand corner.

13. Route the paper through the printer feeder using the feeder gear wheels. Ensure it is centered.

14. Secure the printer shield over the Printer Module using double-sided tape. The notch in the shield should match with the notch in the case.

15. Add the printer cover to the Upper Case and route the printer paper through the opening.

9-4   Bezel Assembly Dis/Assembly

Tools required:
*   none

Disassembly

1. Push the two locking tabs on rear side of Bezel inward and lift upward.

Note

The Bezel is connected to the Processor PCB by a 30-pin flex cable.

---

2. While lifting the rear of the Bezel upward, move the front of the Bezel backward to clear the front of the instrument case.

3. Rotate the front of the Bezel upward to gain access to P5, the 30 pin flex cable.

Caution

When removing the Bezel only apply force to the connector. Pulling on the cable itself will damage the cable assembly resulting in the loss of continuity.

---

4. Disconnect P5 from the Processor PCB by pushing the center disconnect plastic clip on the connector header (at the end of the flex cable). Pull the cable connector out of the connector housing while pushing the disconnect plastic clip. *(Note: store the Bezel PCB side up to prevent damage to the cable.)*

Assembly

5. Position the Bezel front locating pins into place.

6. Connect P5, the 30-pin connector, to the Processor PCB.

NOTE

Make sure that all of the pins are aligned into the connector prior to seating the connector. Failure to do could cause one or more of the connector pins to become bent. If a pin is bent, it may be straightened. If the pin should break it will require the replacement of the Main PCB

7. Rotate the Bezel backward until the rear tabs engage.

9-5   Fixed Table Dis/Assembly

Tools required:
- none

Note

Moving Table should be in home position, which is Down

Disassembly

1. Remove the Push Bar, section 9-2.

2. Grip the left side of the Fixed Table with your left thumb and index finger and the right side of the Fixed Table with your right thumb and index finger. Pull forward with your thumb and index fingers while applying backward pressure to the Lower Case with your middle fingers.

Assembly

3. Grip the left side of the Fixed Table with your left-hand and the right side of the Fixed Table with your right hand. Align the Fixed Table Rails (mounted on bottom of table) into the Lower Case Rail Guides on both sides of the Fixed Table. Push forward evenly until the Fixed Table is completely installed (Snaps into place).

4. Install the Push Bar, section 9-2.

9-6   Moving Table Dis/Assembly

Tools required:
- none

Disassembly

1. Remove Push Bar, section 9-1.

2. Remove the Fixed Table, section 9-5.

3. While gripping the left side of the Moving Table with your left-hand and the right side of the Moving Table with your right hand, pull forward gently until the Moving Table is clear.

Assembly

4. While gripping the left side of the Moving Table with your left-hand and the right side of the Moving Table with your right hand, align the Moving Table onto the Drive Housing and gently push onto housing.

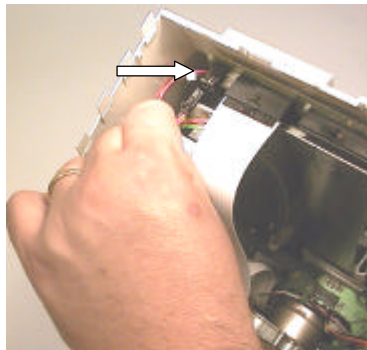5. Reinstall the Fixed Table and Push Bar.

9-7   Upper Case Dis/Assembly

Tools required:

- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module, section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove 4 Phillips screwdriver head screws that secure the Upper Case to the frame. Two in the rear of the upper case, one in the front lower left corner and onre screw in front of the printer.

6. Unplug the fan connector from the Processor PCB.

7. Lift the Upper Case straight up being very careful of the main PCB.

Assembly

8. Set the Upper Case onto the instrument.

9. Plug the fan connector into J1 on the Processor PCB.

10. Install the one Phillips screwdriver head screw that secures the lower front left corner of the Upper Case to the frame and the one in front of the printer.

11. Install the two Phillips screwdriver head screws that secure the rear Upper Case to the frame.

12. Install the Moving Table, section 9-6.

13. Install the Fixed Table, section 9-5.

14. Install the Bezel Assembly, section 9-4.

15. Install the Printer Module, section 9-3.

16. Install the PCMCIA Card, section 9-2.

9-7-1 Fan Assembly Dis/Assembly

Tools required:

- Screwdrivers:#2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver

Disassembly

1. Disassemble the Upper Case, section 9-8.

2. Remove the four hex nuts, located on the inside of the Upper Case, from the four Phillips screwdriver head screws.

3. Remove the locking washers from the four Phillips screwdriver head screws.(Note the configuration)

4. While holding the Fan Assembly, remove the four fan screws.

Note

There is a ground strap mounted on the inside left lower screw.

The rear Fan Guard will come off when the last screw is removed.

Assembly

5. Install the Fan Assembly with the fan's manufacturer name and model number facing outward and horizontal so that it can be read from the rear of the instrument.

6. The P1 connector and wire should face up while holding the fan to the inside of the Upper Case. Install and hold the Fan Guard at the rear of the instrument.

7. Install one of the four Phillips screwdriver head screws through the upper left corner of the Fan Guard and the Fan Assembly.

8. Install the remaining locking washers and hex nuts.

9. Install the ground strap at the left lower corner of the fan between the case and the fan.

10. Secure with screw washer and nut.

11. Install the other two screws, washers and nuts.

12. Install the Upper Case, section 9-7.   top of chapter

9-8 Table Guide-Left Dis/Assembly

Tools required:
- Screwdrivers:#2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table and Moving Table, sections 9-5 and 9-6.

5. Remove the Upper Case, section 9-7.

6. Remove the three Phillips screwdriver head screws that secure the Table Guide to Mounting Plate (two on left side, one on right side.)

7. Disconnect the optical sensor connector from the Mother PCB.

8. Remove the Table Guide.

Assembly

9. Position the Table Guide onto instrument Baseplate using the locating pins on the guide.

10. Secure the Table Guide to the Mounting Plate, two screws on left side and one on right.

11. Connect the optical sensor connector to P10 on the Mother PCB. The sensor wire should go between the Push Bar Rail Support and the Push Bar Slide. Secure the wires with the two plastic clips. Check that there is no interference with the Push Bar.

12. Install the Upper Case, section 9-7.

13. Install the PCMCIA Card, section 9-2.

14. Install the Moving and Fixed Table, sections 9-5 and 9-6.

15. Install the Bezel Assembly, section 9-4.

16. Install the Printer Module, section 9-3.

15. Install the Bezel Assembly, section 9-4.

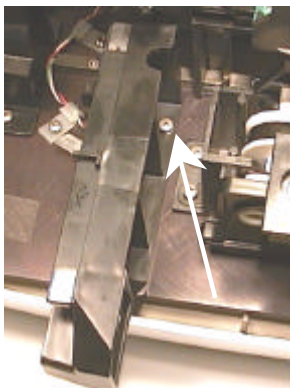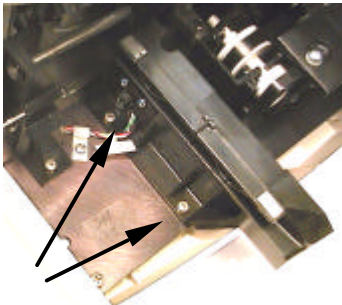16. Install the Printer Module, section 9-3. top of chapter

9-9   Table Guide-Right Dis/Assembly
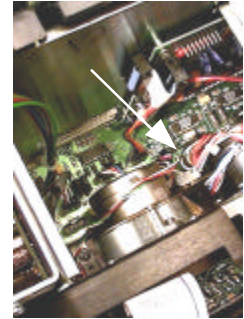
Tools required:

• Screwdrivers: #2Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver

Disassembly

1. Remove the PCMCIA Card, section 9-3.

2. Remove the Printer Module section 9-4.

3. Remove the Bezel Assembly, section 9-5.

4. Remove the Fixed and Moving Tables, section 9-6 and 9-7.

5. Remove the Upper Case, section 9-8.

6. Remove the three Phillips screwdriver head screws that secure the Table Guide to the Mounting Plate (two on left side, one on right side.)

Note

To gain access to these screws, move the Readhead Carrier Assembly toward the rear of the instrument for the front screw and to the front for the rear screws.

---

7. Disconnect the cable coming from the table sensor going to the Mother PCB connector P11.

8. Remove the Table Guide. The Table Sensor cable must be guided through its hole in the Table Guide.

Assembly

9. Feed the Table Sensor cable through the pass through hole in the Table Guide. Position the Table Guide on the Baseplate using the pins on the Table guide.

10. Reconnect the Table Sensor cable to connector P11 on the Mother PCB.

11. Secure the Table Guide to the Mounting Plate, two screws on left side and one on right.

12. Install the Upper Case, section 9-7.

13. Install the PCMCIA Card, section 9-2.

14. Install the Moving and Fixed Tables, section 9-5 and 9-6.

9-10 Power Supply Dis/Assembly

Tools required:
- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Upper Case, section 9-7.

6. Disconnect the Power Supply cable which goes to the Mother PCB. (P6 to J6 on the top left side of the Processor PCB)

7. Remove the Phillips screwdriver head screw that connects the grounding strap from the power supply to the left rear corner of the Baseplate assembly.

8. Remove the Phillips screwdriver head screw that holds the top of the Power Supply to the Electronic Mounting Bracket.

9. Lift the Power Supply upward to gain access to the connector for TB1. Disconnect the cable from connector TB1 and remove the Power Supply.

Assembly

NOTE
If the power supply is being replaced transfer the Grounding strap from the old power supply to the new power supply

10. Lower the Power Supply into the instrument at the left rear corner. The open component side faces left with TB2 at the top.

11. Once the Power Supply is low enough, connect the main power cable to TB1.

-

12. Continue to lower the Power Supply onto the bottom mounting taps.

Mounting tabs

The bottom of the Power Supply frame rests on two mounting tabs located at the bottom of the Electronic Mounting Bracket.

13. Install the Phillips screwdriver head screw that holds the top of the Power Supply to the Electronic Mounting Bracket. Tighten to a torque of 5 inch-pounds.

14. Install the Phillips screwdriver head screw for the Power Supply grounding strap to the left rear corner of the Baseplate assembly.

15. Connect The Power Supply connector J12 to the connector P12 on The Mother PCB.

16. Connect P6 to J6 on the top left side of the Processor PCB.

17. Install the Upper Case, section 9-8.

18. Install the PCMCIA Card, section 9-3.

19. Install the Moving and Fixed Tables, sections 9-7 and 9-6.

20. Install the Bezel Assembly, section 9-5.

21. Install the Printer Module, section 9-4.

9-11   Processor PCB (Main) Dis/Assembly

Tools required:
- Scredrivers: #2 Phillips screwdriver for M4 screws, all others use a #1Phillips screwdriver
- Torque Driver

Disassembly
1. Remove the PCMCIA Card, section 9-3.
2. Remove the Printer Module section 9-4.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed and Moving Tables, sections 9-5 and 9-6.

5. Remove the Upper Case, section 9-7.

6. Disconnect the two cables, J6 and J2, on top of the Processor PCB.

7. Disconnect the cable (part number 40453225) located in center of the Processor PCB looking as viewed from front.

Connector

The connector plugs onto the Processor PCB by going through the Electronic bracket assembly first.

8. Position the instrument so that the back is facing you.

9. Remove the four screws holding the PCB to the Electronic Bracket.

10. The Processor PCB plugs into the Mother PCB with two connectors J1 and J2. Gently lifting the Processor PCB upward will disconnect it from the Mother PCB.

Assembly

11. Position the instrument so that the back is facing you.

12. Plug the Processor PCB onto the connectors, J1 and J2, by gently pressing on the top edge of the PCB.

13. Install the four screws (SEMS) holding PCB to electronic bracket. Tighten to a torque of 5 inch-pounds.

NOTE

The screw above the PCMCIA card requires a lock washer between the screw head and the PCB

14. Position the instrument so that the back is facing you.

15. Connect the Printer Interface Assembly cable to J3 located in center of the Processor PCB looking from the front.

16. Connect the Strip Detector to J6 on the top left side of the Processor PCB.

17. Connect the Pre-amp A/D to J2 on the top right side of the Processor PCB.

18. Install the Upper Case, section 9-7.

19. Install the PCMCIA Card, section 9-2.

20. Install the Moving and Fixed Tables, section 9.6 and 9-5.

21. Install the Bezel Assembly, section 9-4.

22. Install the Printer Module, section 9-3. top of chapter

9-11-1   SIMM PCB Dis/Assembly
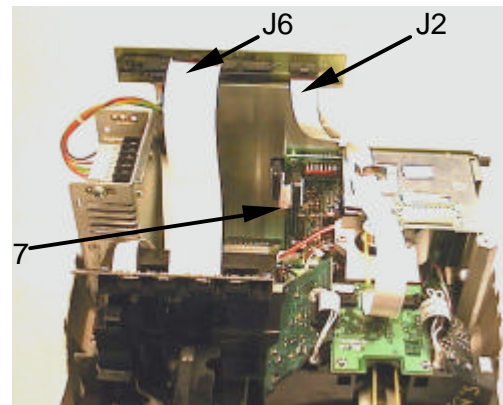
CAUTION

The SIMM processor must be programmed as follows, failure to do so will lead to damage of the Strip Detector on initial instrument power up.

1) Install the new SIMM processor

2) Disconnect the strip detector cable from the Main Processor PCB (Cable J6)

3) Install the Display into the Display Test Stand and reconnect the display.

4) Reconnect the power cord; install the Instrument Test Card (section 9-2).

5) Turn the instrument "ON". When it asks to reprogram the instrument, respond "YES."

6) When reprogramming is complete, turn the power off, remove the Instrument Test Card disconnect the power cord and reconnect the Strip Detector Cable J6.

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed and Moving Tables, section 9-5 and 9-6.

5. Remove the Upper Case, section 9-7.

6. Position the instrument so that the back is facing you.

7. Locate the SIMM PCB at the right side of the PCB.

8. The SIMM PCB is plugged into a vertical holder. At the top and bottom of the SIMM PCB Holder there is a metal clip that secures the PCB.

9. Push the metal clips to disengage the SIMM PCB. As the clips are pushed, the PCB will move outward.

10. Grip the SIMM PCB by the edges and remove it from the holder.

Assembly

11. Insert the SIMM PCB at a 45-degree angle. Plug the SIMM PCB into the holder.

12. Push the SIMM PCB gently into position until the metal clips secure the PCB.

13. Install the Upper Case, section 9-7.

14. Install the PCMCIA Card, section 9-2.

15. Install the Moving and Fixed Tables, section 9-6 and 9-5.

16. Install the Bezel Assembly, section 9-4.

17. Install the Printer Module, section 9-3.   top of chapter

9-12 Electronics Bracket Dis/Assembly

Tools required:

- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Upper Case, section 9-7.

6. Unplug the Strip Detector cable (J6) and the cable coming from the A/D PCB (J2) from the Processor PCB. Also disconnect the power cable going to the Printer Interface PCB from the Mother PCB at connector P7 on the Mother PCB.

7. From the rear of the instrument, remove one screw on left side securing the bracket to the Lower Case. This screw goes through a grounding strap.

8. Loosen the two screws on the right side.

Note

These screws are designed to stay with the assembly when they are unscrewed. As they are loosened, an inner spring pushes them upward. Once they are loose, just leave them seated in hole

    a. The first screw is located next to the Power Supply on the inside.

    b. One screw is at the right rear of the bracket, next to the main power plug

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9. Remove the screw from the base plate connected to the power supply grounding strap.

10. Remove the screw connecting the main power ground wire to the bracket next to the main power connector.

11. Disconnect the input power cable from the Power Supply.

12. At the Power Supply disconnect the cable going to the Mother PCB.

13. Remove the Electronics Bracket Assembly.

Assembly

14. Set The Electronics Bracket Assembly in place.

Caution
Take care not to pinch any wires or bend any pins.

15. Reconnect the grounding strap from the power supply to the Baseplate on right side (from rear) of the instrument.

16. Connect the main power ground wire to the bracket next to the main power in. Tighten the screw to a torque of 5 inch-pounds.

17. Connect the main power cable to the Power Supply input connector and the power cable going to the Mother PCB to the Power Supply output connector.

18. Reconnect the power cable for the Printer Interface PCB to connector P7 on the Mother PCB.

19. Tighten the two screws on the right side.

  a. One screw is at the right rear of the bracket, next to the main power plug.

  b. The second screw is located next to the Power Supply on the inside.

20. From the rear of the instrument, install the one screw on left side securing the bracket to the Lower Case. This screw goes through a grounding strap.

21. Reconnect the cables going to the Main Processor PCB from the Strip Detector (J6) and the A/D PCB (J2).

22. Install the Upper Case, section 9-7.

23. Install the PCMCIA Card, section 9-2.

24. Install the Moving and Fixed Tables, section 9-5 and 9-6

25. Install the Bezel Assembly, section 9-4.

26. Install the Printer Module, section 9-3   top of chapter

9-13   Mother PCB Dis/Assembly

Tools required:

- Screwdrivers; #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver
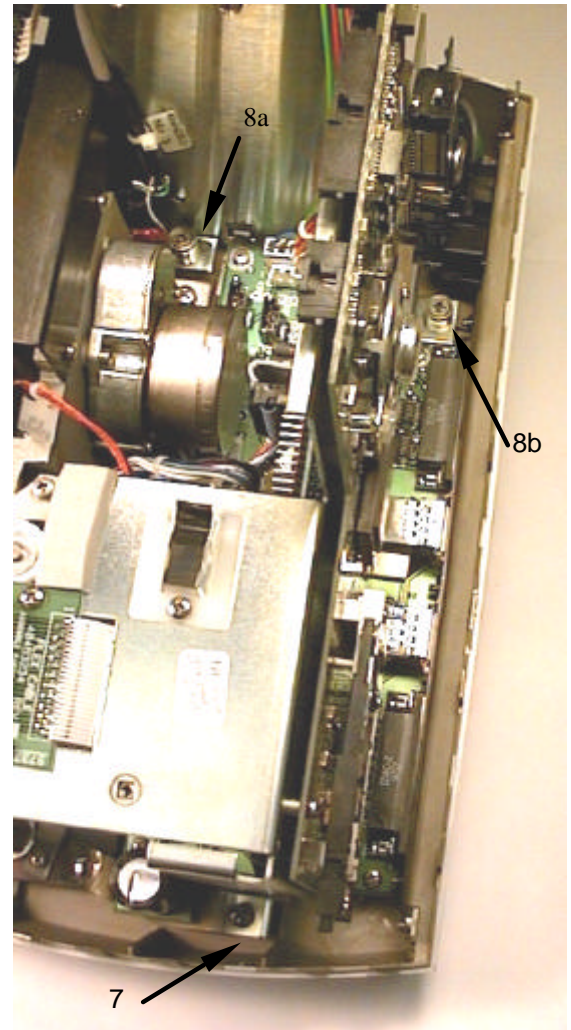- New conductive gasket (50184582)

Disassembly

1.   Remove the PCMCIA Card, section 9-2.

2.   Remove the Printer Module section 9-3.

3.   Remove the Bezel Assembly, section 9-4.

4.   Remove the Fixed Table and Moving Table, sections 9-5 and 9-6

5.   Remove the Upper Case, section 9-7.

6.   Remove the Electronics Bracket, section 9-12.

7.   Disconnect the Strip Detector Flex Cable, P8, going to the Mother PCB.

8.   Disconnect the optical sensors and motors;

   a.   Fixed Table sensor, P10, from the Mother PCB.

   b.   Crank Arm Sensor, P9, from the Mother PCB.

   c.   Push Arm Motor, P14, from the Mother PCB.

   d.   Readhead Drive Motor, P15, from the Mother PCB.

   e.   Moving Table Motor, P13, from the Mother PCB.

   f.   Moving Table Sensor, P11, from the Mother PCB.

9. Remove the six screws securing the Mother PCB to the Lower Case.

Note

When facing the rear of the instrument the two screws on the right hand side require lock washers between the screw head and the PCB.

10. Remove the three rear screws securing The Mother PCB back plate to the rear of the Lower Case.

Hint

Removing the Baseplate Assembly allows for easier removal and installation of the Mother PCB.

11. Carefully move the Mother PCB inward, which will allow enough room for the RS232 connector and Centronics connector on the PCB to miss the outer edge of the Lower Case.

12. Gently lift the rear of the PCB upward and out to remove.

13. Remove the conductive gasket between the back plate of the Mother PCB and the inside back wall of the Lower Case.

Assembly

14. Install a new conductive gasket. This goes between the rear inner Lower Case wall and the rear of the Mother PCB.

15. Position the Mother PCB onto the Lower Case and insure that gasket is in proper position.

16. Install the six screws securing the Mother PCB to the Lower Case.

17. Install the three rear screws securing The Mother PCB back plate to the back of the Lower Case. Tighten the screws to a torque of 7 inch –pounds.

18. Connect the Strip Detector Flex Cable to P8 on the Mother PCB.

19. Connect the optical sensors and motors;

   a. Fixed Table sensor to P10 on the Mother PCB.

   b. Crank Arm Sensor to P9.

   c. Push Arm Motor to P14.

   d. Readhead Drive Motor to P15.

   e. Moving Table Motor to P13.

   f. Moving Table Sensor to P11.

20. Install the Electronics Bracket, section 9-12.

21. Install the Upper Case, section 9-7.

22. Install the PCMCIA Card, section 9-2.

23. Install the Moving and Fixed Tables, section 9-5 and 9-6.

24. Install the Bezel Assembly, section 9-4.

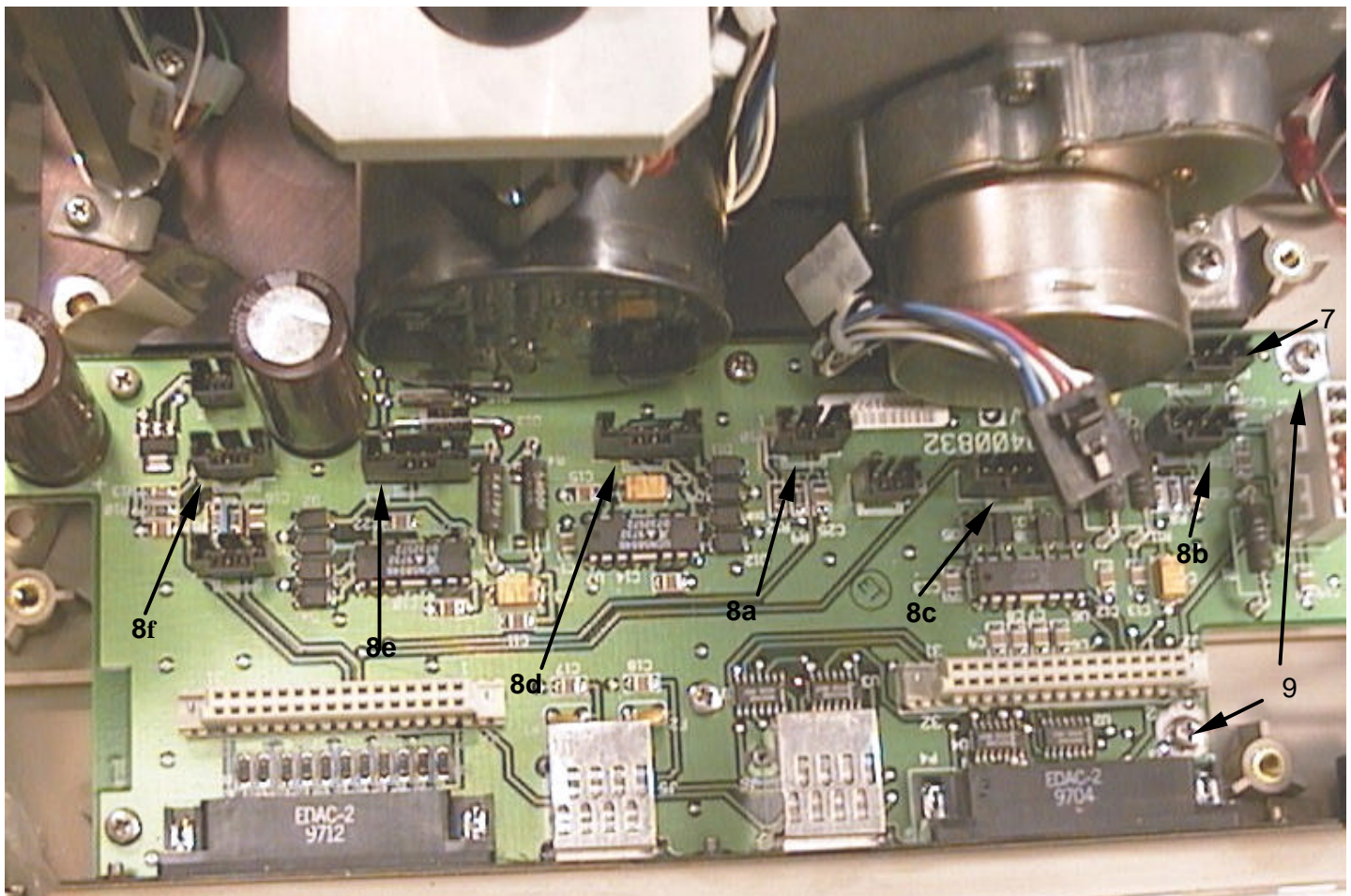25. Install the Printer Module, section 9-3 top of chapter

9-14   Strip Detector Dis/Assembly

Tools required:

- Screwdrivers; #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Right angle Phillips screwdriver screwdriver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-34.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Upper Case, section 9-7.

6. Disconnect the detector flex cable from J6 on the top left side of the Processor PCB.

7. Disconnect the detector flex cable from P8 on

the Mother PCB.

8. Using a right angle Phillips screwdriver screwdriver, remove the two Phillips screwdriver head screws holding the Strip Detector Bracket to the casting.

Note

To gain access to the left-hand detector screw , remove the top securing screw from the Power Supply. This allows the Power Supply to be moved to the left to gain access to the detector screw.

Hint

8A. An alternative to removing the bracket is to remove the Strip Detector PCB from the bracket. Removing the two Phillips screwdriver screws that secure it to the Bracket accomplishes this.

9. Remove the Strip Detector Assembly.

Assembly

10. Install the Strip Detector Assembly with the flex cable at the bottom of strip. The bracket must fit in to the ledge on the casting.

Note

The Strip Detector Housing Assembly (black piece covering detectors) is keyed at one end.

11. Install the two Phillips screwdriver head screws holding the Strip Detector Bracket to the casting.

12. Connect the 5-pin flex cable P8 on the Mother PCB.

Note

For ease of connecting other cables, connect the 5-pin flex cable first.

13. Connect the 12-pin flex cable to J6 on the Processor PCB.

14. Install the Upper Case, section 9-7.

15. Install the PCMCIA Card, section 9-2.

16. Install the Moving and Fixed Tables, sections 9-6 and 9-5.

---

17. Install the Bezel Assembly, section 9-4.

18. Install the Printer Module, section 9-3.

9-15   Lamp Assembly Dis/Assembly

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Cotton gloves

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Upper Case, section 9-7.

6. Disconnect P4 (right Lamp Assembly) or P5 (left Lamp Assembly) from the Pre-amp A/D PC Assembly.

Caution

Cotton gloves MUST be worn when handling the Lamps, Pre-amp PCBs and A/D PCB. Powder from latex gloves, Oil and dirt from skin will cause imprecision in readings.

Static precautions must be observed when working on the instrument with the Upper Case removed.

---

7. Both lamps have a plastic lamp-securing arm. To remove the lamp, gently pull the locking arm away from the lamp until the lamp clears the arm.

8. Remove the lamp.

Assembly

Note

Lamps should be replaced in pairs

---

9. Install the Lamp Assembly. Both lamps have a plastic locking arm to secure them in place.. To Install the lamp, gently pull locking arm way from lamp holder and insert the lamp.

10. Route the lamp cables are under the Pre-Amp flex cables and insure that plugs P5 and P6 lock into the mating connectors on the A/D PCB. Check that neither the flex cables or the lamp cables will come in contact with the inside of the hood area of the Upper Case.

11. Install the Upper Case, section 9-7.

12. Install the PCMCIA Card, section 9-2.

13. Install the Moving and Fixed Tables, sections 9-6 and 9-5.

14. Install the Bezel Assembly, section 9-4.

15. Install the Printer Module, section 9-3.   top of chapter

9-16   A/D PCB and Pre-amp PCB Dis/Assembly

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Cotton gloves
- Torque Driver

9-16-1 A/D PCB

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed and Moving Tables, section 9-5 and 9-6.

5. Remove the Upper Case, section 9-7.

6. Disconnect P4 (right Lamp Assembly) & P5 (left Lamp Assembly) from the Pre-amp A/D PC Assembly.

7. Both lamps have a plastic securing arm. To remove the lamp, gently pull locking arm away from lamp until the lamp clears the arm.

8. Remove the lamps.

9. Disconnect the flex cable from J2 on the Processor PCB.

10. Disconnect the flex cables from the left and right Pre-amp PCB. Lifting the outer housing of the ZIF connector will unlock it allowing the flex cable to be removed.

11. Remove the two screws securing the Pre-amp A/D Interconnect PCB to "Readhead. Also remove the cable and foam from the securing clip on the electronics bracket.

Assembly

12. Set Pre-amp A/D on top of Readhead Carrier Assembly and align the screw holes.

13. Install the two screws securing the Pre-amp A/D to "Readhead Carrier Assembly" and tighten to a torque of 7 inch-pounds.

14. Connect the 12-pin flex cable to J2 on Processor PCB and re-route the cable neatly through the cable clip.

15. Install the Lamp Assembly's, section 9-15.

16. Connect the lamp connectors P4 and P5 to Pre-amp A/D Interconnect PCB Assembly. Install the Flex cables into the ZIF connector on the Pre-amp PCBs.

17. Install the Upper Case, section 9-7.

18. Install the PCMCIA Card, section 9-2.

19. Install the Moving and Fixed Tables, sections 9-6 and 9-5.

20. Install the Bezel Assembly, section 9-4.

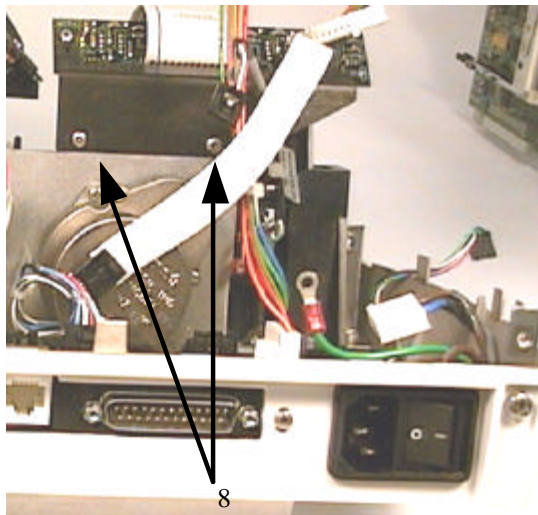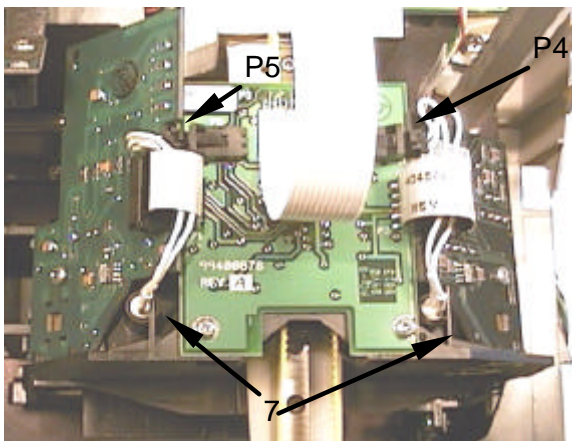21. Install the Printer Module, section 9-3. *top of chapter*

9-16-2 Pre-amp PCBs

Note

It is easier to remove and install the Pre-amp PCBs with the A/D PCB removed.

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Cotton gloves
- Torque Driver

Caution

Cotton gloves MUST be worn when handling the Lamps, Pre-amp PCBs and A/D PCB. Powder from latex gloves, Oil and dirt from skin will cause imprecision in readings.

Static precautions must be observed when working on the instrument with the Upper Case removed.

Disassembly

1. The Pre-amp PCBs are attached to the black plastic readhead body by one screw (1A) and two tabs molded into the readhead (1B) (See photos of the Left and Right Pre-amps). Removing the screw allows the Pre-amp PCBs to be separated from the readhead body.

Left Pre-Amp PCB

CAUTION

When removing or installing the screw which secures the Pre-amp PCBs, the readhead body must be supported from underneath to prevent it from breaking.

Right Pre-Amp

Assembly

2. Move the readhead body to the front of the instrument.

3. Position the Pre-amp PCB in place and fasten with the screw. Tighten the screw to a torque of 7 inch-pounds.

Note

Make sure that the left Pre-amp PCB does not "Droop". If the rear of the PCB hangs down it may run into the Slider Arm (see Baseplate assembly in the chapter 10).

---

4. Reconnect the flex cables coming from the A/D PCB and continue with the assembly procedure for the A/D PCB from section 9-16-1.

HINT

You may find it easier to install the flex cables from the A/D PCB into the Pre-amps before installing any of the PCBs onto the readhead body. You can then install the three PCB assembly starting with the Left Pre-amp, next the A/D PCB and finishing with the Right Pre-amp PCB. top of chapter

---

9-17   Drive Housing Dis/Assembly

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Hex wrench 5/64

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed and Moving Tables, sections 9-5 and 9-6.

5. Remove the Upper Case, section 9-7.

6. Remove the Left Table Guide Assembly, section 9-8.

7. Move the Readhead Carrier Assembly to the rear position on the instrument.

8. Remove the two Phillips screwdriver head screws securing the Drive Housing on the left and two screws on right.

9. Disconnect the optical sensor from The Mother PCB.

Coupling

9

Note

A Flexible Coupling connects the Drive Housing Assembly to the stepper motor shaft.

Hint

You may find it necessary to loosen one half of the Flexible coupling to remove the Drive Housing assembly. To do this:

Rotate the coupling so that the setscrews are at the 1 o'clock position.

Use a 5/64 Hex wrench to loosen the setscrew of the coupling on the shaft coming from the Drive Housing assembly.

Slide that half of the coupling towards the Drive Housing assembly on the shaft.

Caution

On the bottom of the Drive Housing Assembly, there are two pins that key the housing into the Baseplate. The housing must gently be lifted upward to disengage these pins.

Do not use the front rotating plate of the Drive Housing for lifting, use the sides of the Drive Housing.

10. Gently lift the left side of the housing upward until you feel the left tab come out of the Baseplate hole.

11. Holding the left side of the housing with your left hand, place your right hand on the right side of the housing. Gently lift upward with your right hand while gently twisting upward with your left hand.

12. Remove the housing and guide the optical sensor cable through the hole in the right table guide.

Assembly

13. Guide the optical sensor wire through the hole in the side of the Right-hand Table Guide directly above the screws holding the sensor onto the Table Guide.

14. Slide the housing gear into the Flexible Coupler.

Caution

Do not push on the Moving Table Plate.

---

15. Holding the left side of the housing with your left hand, push on the right side of the housing until the right tab falls into the Baseplate positioning hole. When the right side is in, push on left side of housing until you feel the left side fall into position.

16. Make sure that the table sensor flag is centered between the sensor arms.

17. Plug the sensor wire into P11 on the Mother PCB.

18. Install the two Phillips screwdriver head screws securing the Drive Housing on the left and two screws on right.

19. Install the Left Table Guide Assembly, section 9-8.

20. Install the Upper Case, section 9-7.

21. Install the PCMCIA Card, section 9-2.

22. Install the Moving and Fixed Tables, sections 9-6 and 9-5.

23. Install the Bezel Assembly, section 9-4.

24. Install the Printer Module, section 9-3.

25. Perform strip centering setup and the strip walk test.   top of chapter
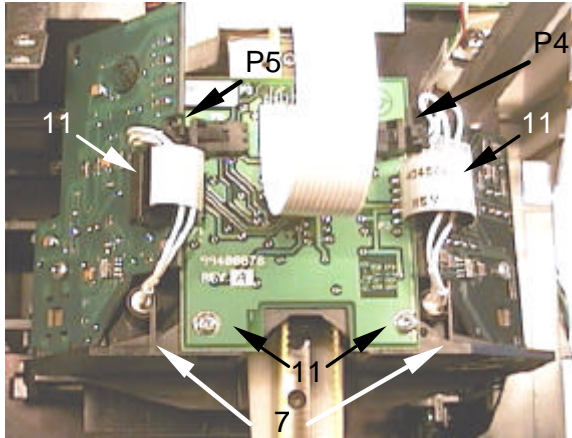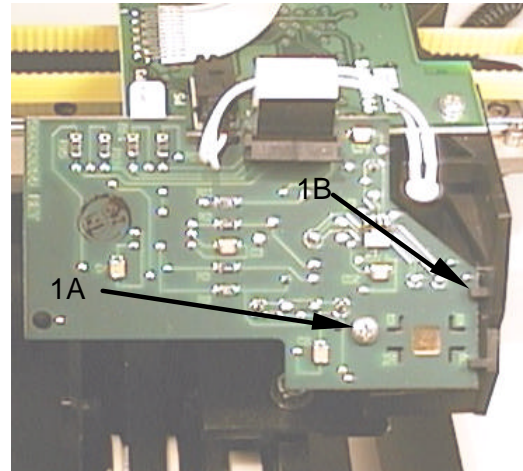
9-18   Crank Arm Dis/Assembly

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- .050 inch Hex wrench
- Torque Driver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Moving Table, section 9-6.

6. Remove the Upper Case, section 9-7.

7. Move the Readhead to the front of the instrument.

8. Rotate the Crank Arm so that it points to the right side of the instrument. This will also move the Slider Arm to the right.

Note

Refer to the Baseplate Assembly in the illustrated parts break down.

9. Remove the Phillips screwdriver head screw which holds the Shaft in place.

10. Slide the shaft to the left.

11. Tilt the Slide Arm forward (to clear the Strip Detector assembly) and lift up. This will remove the Slide Arm from the instrument

12. Loosen the set screw (now located at the 12 O-clock position) with the "short arm" of a .050 inch Hex wrench.

13. Pull the Crank Arm off the Push Arm Drive Motor Shaft.

Assembly

14. Push the Crank Arm onto the Push Arm Drive Motor shaft. Align the flat spot of the Crank Arm with the flat spot of the motor shaft.

15. Align front of motor shaft with front of Crank Arm.

16. Tighten setscrew..

17. Position the Slider Arm so that it engages the Guide Rail on the Baseplate and that the Shaft is aligned with its hole.

18. Slide the Shaft through the Slider Arm and into its support on the Motor Casting. Install the lock washer and Phillips screwdriver head screw to secure the Shaft in place. Tighten the screw to 8 inch pounds of torque.

Note

Grease is to be applied to the shaft. Reference section 5 for greasing shaft.

19. Install the Upper Case, section 9-7.

20. Install the PCMCIA Card, section 9-2.

21. Install the Moving Table, section 9-6

22. . Install the Fixed Table, section 9-5.

23. Install the Bezel Assembly, section 9-4.

24. Install the Printer Module, section 9-3. top of chapter

9-19   Baseplate Mechanism Dis/Assembly

Tools required:
- Screwdrivers: #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Moving Table, section 9-6.

6. Remove the Upper Case, section 9-7.

7. Remove the five (M4x12) Phillips screwdriver head screws, one at each corner and one in middle of Mounting Plate.

Note

Two screws in the left and right rear corners go through grounding straps.

---

7. Disconnect the two Strip Detector Flex Cables, one from the Processor PCB and one from The Mother PCB.

8. Disconnect the Pre-amp A/D Flex Cable from Processor PCB.

Hint

Better access to the connectors on the Mother PCB is obtained by moving the Baseplate Assembly slightly forward of its mounting position for the disconnection and connection of the cables.

---

9. Disconnect the optical sensors and motors;

    g. Fixed Table Sensor, P10, from the Mother PCB.

    h. Crank Arm Sensor, P9, from the Mother PCB.

    i. Push Arm Motor, P14, from the Mother PCB.

    j. Readhead Drive Motor, P15, from the Mother PCB.

    k. Moving table Motor, P13, from the Mother PCB.

    l. Moving Table Sensor, P11, from the Mother PCB.

10. Gently lift the Baseplate Mechanism Assembly upward. Use the Right Hand Table Guide and the Push Arm Rail Support for lifting. By lifting straight upward, the Readhead Motor Assembly Pulley will miss the Electronic Mounting Bracket Top.

Assembly

11. If the Baseplate Assembly is replaced, transfer the instrument Serial Number label from the old Baseplate to the new Baseplate. Affix the label to the left front top corner of the assembly.

12. Use the Right Hand Table Guide and the Push Arm Rail Support to lift, gently set the Baseplate Mechanism Assembly into position.

13. Reconnect the sensor and motor cables to the Mother PCB;

14. Fixed Table Sensor, P10, to The Mother PCB.

15. Crank Arm Sensor, P9, to The Mother PCB.

16. Push Arm Motor, P14, to The Mother PCB.

17. Readhead Drive Motor, P15, to The Mother PCB.

18. Moving table Motor, P13, to The Mother PCB.

19. Moving Table Sensor, P11, to The Mother PCB.

20. Connect the Pre-amp A/D Flex Cable to Processor PCB.

21. Connect the two Strip Detector Flex Cables, P1 to P8 on The Mother PCB and P2 to J6 on Processor PCB.

22. Install the five (M4x12) Phillips screwdriver head screws. One at each corner and one in middle of Mounting Plate. The screws should be tightened to a torque of 18 inch pounds and 12 inch pounds for the ground strap at the card.

23. Install the Upper Case, section 9-7.

24. Install the PCMCIA Card, section 9-2.

25. Install the Moving and Fixed Tables, sections 9-6and 9-5.

26. Install the Bezel Assembly, section 9-4.

27. Install the Printer Module, section 9-3.   top of chapter

9-20   Lower Case Dis/Assembly

Tools required:
- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver

Disassembly

1. Remove the PCMCIA Card, section 9-2.
2. Remove the Printer Module section 9-3.
3. Remove the Bezel Assembly, section 9-4.
4. Remove the Fixed Table, section 9-5.
5. Remove the Moving Table, section 9-6.
6. Remove the Upper Case, section 9-7.
7. Remove the Electronics Bracket, section 9-12
8. Remove the Baseplate Mechanism, section 9-19.
9. Remove the Mother PCB, section 9-13.

Assembly

10. Position The Mother PCB onto the Lower Case.
11. Install the six screws securing The Mother PCB to the Lower Case.
12. Install the three rear screws securing the Mother PCB back plate and new conductive Gasket to back of Lower Case. Tighten the screws to a torque of 7 inch-pounds.
13. Use the Right Hand Table Guide and the Push Arm Rail Support to lift, gently set the Baseplate Mechanism Assembly into position.

Note

Before setting assembly in place secure the wires and cables so as not to be in the way.

14. Install the three (M4x12) Phillips screwdriver head screws. One at each front corner and one in middle of Mounting Plate.
15. Connect the optical sensors and motors;
16. Fixed Table Sensor, P10, to The Mother PCB.
17. Crank Arm Sensor, P9, to The Mother PCB.
18. Push Arm Motor, P14, to The Mother PCB.

19. Readhead Drive Motor, P15, to The Mother PCB.
20. Moving table Motor, P13, to The Mother PCB.
21. Moving Table Sensor, P11, to The Mother PCB.
22. Plug in the Strip Detector cable into the Mother PCB.
23. Set Electronics Bracket in place.
24. Connect the main power ground wire to the bracket next to the main power in.
25. Connect the main power cable to The Power Supply.
26. Connect the Power Supply connector J12 to connector P12 on The Mother PCB.
27. Tighten two screws on right side. One screw is at the right rear of the bracket, next to the main power plug. The second screw is located next to the Power Supply on the inside.
28. Install the Phillips screwdriver head screw on the grounding strap at lower front of The Power Supply.
29. From the rear of the instrument, Install the one screw on left side securing the bracket to the Lower Case. This screw goes through a grounding strap (tighten to 12 inch pounds).
30. Other end of grounding strap is screwed to the Baseplate Mechanism.
31. Swivel the instrument so front is facing you.
32. Connect the Strip Detector to J6 on top left side of Processor PCB
33. Connect the Printer Interface PCB power cable to P7 located on the Mother PCB.
34. Connect the Pre-amp A/D to J2 on top right side of Processor PCB.
35. Install the Upper Case, section 9-7.
36. Install the Moving Table, section 9-6.
37. Install the Fixed Tables, section 9-5.
38. Install the Bezel Assembly, section 9-4.
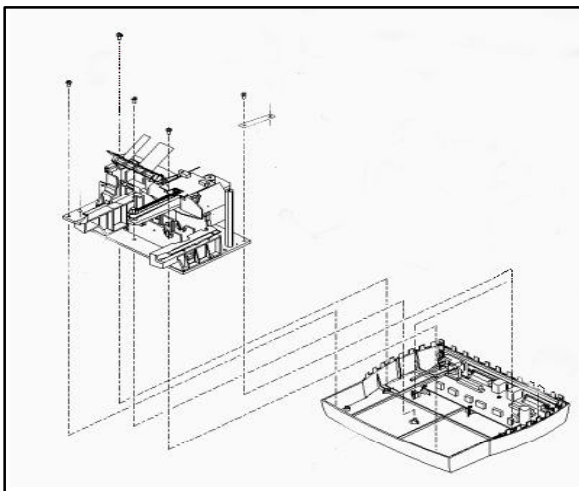39. Install the Printer Module, section 9-3.
40. Install the PCMCIA Card, section 9-2. top of chapter

9-20-1   Power Entry Module Dis/Assembly

<u>Tools required:</u>
- Standard blade

<u>Disassembly</u>

1. Remove the Power Entry Module Assembly. Using the tip of your Phillips screwdriver screwdriver, push on the module locking arm on the inside of Lower Case. Do one side then the other. Pull module out of mounting hole.

<u>Assembly</u>

2. Set Power Entry Module Assembly into hole in back panels so that the ON/OFF Switch is closes to outside edge.

3. Push the module into hole until locking arms on the inside of the Lower Case engage.

4. Assembly the Lower Case Assembly following the steps in section 9-20.

9-21 Touch Screen Dis / Assembly

<u>Tools required:</u>
- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver
- Instrument Test Card

<u>Disassembly</u>

1. Remove the Bezel Assembly, section 9-5

2. Place the Bezel Assembly face down on a work surface. Disconnect the Touch Screen flex cable from the Display Interface PCB.

3. Remove the 4 Phillips screwdriver screws that secure the Display / Touch Screen assembly to the Bezel

4. Remove the Display / Touch Screen assembly.

5. Separate the Touch Screen from the Display.

<u>Assembly</u>

6. Clean the Display off.

7. Remove the protective backing from the new Touch Screen and position into the Bezel.

8. Position the Display into the Bezel and install the Display mounting bracket. Tighten the 4 Phillips screwdriver screws to a torque of 7 inch pounds.

9. Reconnect the Touch Screen flex cable to the Display Interface PCB.

10. Assemble the Bezel Assembly into the Upper Case, section 9-4

11. Install the Instrument Test Card and verify operation of the Display and Touch Screen, sections 7-3-4-3 and 7-3-4-5. top of chapter

5

9-22 Internal Printer Interface PCB
Dis / Assembly

Tools required:
- #2 Phillips screwdriver for M4 screws, all others use a #1 Phillips screwdriver
- Torque Driver
- Instrument Test Card

Disassembly

1. Remove the PCMCIA Card, section 9-2.

2. Remove the Printer Module section 9-3.

3. Remove the Bezel Assembly, section 9-4.

4. Remove the Fixed Table, section 9-5.

5. Remove the Moving Table, section 9-6.

6. Remove the Upper Case, section 9-7.

7. Remove the Electronics Bracket, section 9-12

8. Disconnect the power cable from connector CN5

9. Disconnect the Cable from connector CN1.

10. Disconnect the printer extension cable from connector CN4a

11. Remove the four Phillips screwdriver head screws holding the Interface PCB to the Electronics bracket.

Assembly

13. Install the new interface PCB assembly to the electronics bracket assembly and secure with

the four Phillips screwdriver head screws. Tighten the screws to a torque of 5 inch-pounds.

14. Reconnect the following cables: Power cable to connector CN5, Jumper cable to connector CN1 and the printer extension cable to connector CN4a.

NOTE

When the PCB is installed on the electronics bracket the "ON" position of the DIP switchs is in the "Down" position. The switch settings are as follows.

1=On, 0=Off

Switch	position 1 2 3 4 5 6 7 8
SW1	1 1 1 1 0 0 1 1
SW2	0 0 0 0 0 0 0 0
SW3	1 1 1 0

---

15. Install the Electronics Bracket assembly, section 9-12.

16. Install the Upper Case, section 9-7.

17. Install the Bezel Assembly, section 9-4.

18. Install the Printer Module, section 9-3.

19. Install the PCMCIA Card, section 9-2.

20. Install the Moving and Fixed Tables, sections 9-6and 9-5.   top of chapter

CHAPTER TEN - ILLUSTRATED PARTS BREAKDOWN *Return*

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INSIDE VIEW

ARROW MUST BE
POSITIONED AS SHOWN

UPPER CASE ASSEMBLY - 95002147 top of chapter

Find Number	Description	Part number
1	Upper Case	50080677
2	Exhaust Fan Assembly	40453216
3	Ground Strap	
4	Washer, M3 Locking, External Tooth	
5	Nut, M3 Hex	
6	Guard Fan	
7	Screw, M3 x 30 Phillips Cheese Head	
8	Gasket – Ground	50184583

Exploded View part 1 top of chapter

Find Number	Description	Part number
1	Base Plate Assembly	95002176
2	Gasket- Ground	50184583
3	Screw 4 X 12 Phillips Cheese Head	
4	Ground Strap	
5	Bezel Assembly	95002093
6	Upper Case Assembly	95002147
7	Screw M4X10 Phillips Cheesa HD	
8	Lower Case Assembly	95002174
15	Serial Number Label	

Exploded View part 2   top of chapter

Find Number	Description	Part number
7	Screw M4X10 Phillips Cheesa HD	
8	Lower Case Assembly	95002174
10	Electronics Bracket Assembly	95002148
11	Shield Printer	50551098
12	Tape- Foam	
13	Printer Cover	50062319
14	Printer Thermal	40451012
16	Label- UL / CSA / TUV / EMC / CE	50340726
17	Rating Label	
18	Screw M3 X 8 Phillips Cheese HD	
Not shown	Conductive Gasket for Mother P.C.B.	50184582

Base Plate Assembly 1   top of chapter

Find Number	Description	Part Number
1	Right Table Guide	95002088
2	Drive Housing Assembly	95002066
3	Left Table Guide	95002089
4	Fixed Table Sensor	40453222
5	Push Arm Home sensor	40453233
6	Strip Detector Assembly	95002175
7	Lamp	40453220

.

Base Plate Assembly 2   top of chapter

Find Number	Description	Part Number
1	Screw M3 X 6Phillips Cheese Head	
2	Crank Arm	50003063
3	Rail Guide	50513062
4	Pusher Rail Support	50543207
5	Shaft	50552175
6	Slider Arm	50003062

Readhead Assembly   top of chapter

..

Find Number	Description	Part Number
1	Screw M 3 X 6 Phillips Cheese Head (used in 4 places)	50740154
2	A / D PCB assembly	99400876
3	Left Pre-Amp P.C.B. Assembly	99400875
4	Readhead Carrier Assembly	95002285
5	Right Pre-Amp P.C.B. Assembly	99400834

NOTE: ORANGE WIRE ON ITEM 8 MUST BE ORIENTED AS SHOWN.

ORANGE

Electronics Bracket Assembly top of chapter

Find Number	Description	Part Number
1	Bracket Mounting	50032575
2	Printer Interface PCB Assembly	99400833
3	Cable Assembly Printer Interface Power	40453027
4	Cable Assembly Jumper 20 Pin	40453225
5	Power Supply	40453217
6	Cable Assembly Power Supply / Mother PCB	40453218
7	Cable Assembly Printer Extension	40453234

..

Lower Case Assembly   top of chapter

Find Number	Description	Part Number
1	Grounding Gasket	50184583
2	Power Entry Module	40453213
3	Screw M 3X 8 Phillips Cheese Head	
4	Screw M 4X 10 Phillips Head	
5	Foot	50151014
6	Case – Lower	50080676
7	Mother PCB	99400832
8	Screw M 4X 8 Phillips Head	

PARTIAL END VIEW

Drive Housing Assembly 95002066   top of chapter

.

Find Number	Description	Part Number
1	Screw #4-40 X ¼ Pan Head	
2	Screw #4-24 X.312 Pan Head	
3	Optical Interrupter Assembly	40453221

PIN 1

10.00 +.25 -.25

ALL DIMENSIONS ARE IN INCHES.

PIN 1

ITEM NO. 1 POS. NUMBER	WIRE COLOR	ITEM NO. 3 POS. NUMBER	VOLTAGE
5	ORANGE	6	+ 12V
10	RED	5	+ 5V
9	RED	4	+ 5V
8	GREEN	3	GND
7	GREEN	2	GND
2	DK. BLUE	1	- 12V

3. CABLE ASSEMBLY TO BE 100% TESTED FOR OPENS AND SHORTS. VENDOR TO CERTIFY TESTING.

Power Supply Cable Assembly 40453218   top of chapter

.

ITEM NO. 5 POS. NUMBER	WIRE COLOR	ITEM NO. 1 POS. NUMBER
1	ORANGE	1
2	RED	2
3	BLACK	3

ALL DIMENSIONS ARE IN INCHES.

Cable Assembly Printer Power 40453219   top of chapter

OPTICAL INTERRUPTER WIRE COLOR	CONNECTOR POSITION NUMBER
RED	4
WHITE	3
GREEN	2
BLACK	1

ALL DIMENSIONS ARE IN INCHES.

Optical Interrupter Assembly 40453221   top of chapter

1

THIS END WILL SNAP FIT INTO NOTCH
AFTER INSERTING OTHER END

FIXED TABLE ASSEMBLY AND HOLDDOWN 95002367   top of chapter

Find Number	Description	Part number
1	Holddown	50210070

COILED CABLE, GREY WITH RJ45 CONNECTOR
PSC INC. # LVC980220FF01 ⓐ

1

SPLIT FERRITE WITH GREY
PLASTIC SNAP ON CASE
D.M. STEWARD INC. #28A2024-0A1

82.5 +6.4 -6.4

NOTES: UNLESS OTHERWISE SPECIFIED

1 CABLE MUST PASS THROUGH THE FERRITE TWICE.

2. ALL DIMENSIONS IN MILLIMETERS.

Bar Code Reader Cable 40453237   top of chapter

Find Number	Description	Part number
1	Motor Assembly – Readhead	40453205
2	Motor – Table Drive	40453207
3	Motor – Pusher Arm	40453206
4	Bracket – Readhead Mounting	
5	Screw M3 x10 Phillips Cheese Head	
6	Screw M3 x 12 Phillips Cheese Head	
7	Screw 8 x32 x ¾" Pan Head	

Display Bezel Assembly 95002093 top of chapter

Find Number	Description	Part number
1	Display Interface PCB	99400831
2	Touch Screen Assembly	40453214
3	Bezel	50047609
4	Display	40090104
5	Bracket-Display Mounting	50032584
6	Screw 3X6 Phillips Cheese Head SEMS	
7	Interconnect Cable	40453215

Fixed
Table

Moving
Table

Access slot for
horizontal plate
adjustment screws

Access holes for
horizontal plate
adjustment

Horizontal plate adjustment screw

Horizontal Plate Alignment Fixture 71647012 top of chapter

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CHAPTER ELEVEN – SCHEMATIC DIAGRAMS   *Return*

Page

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HIGHEST REF DES USED	REF DES NOT USED
R16	
C20	
LS1	
U3	
P1	

NOTES:

1. RESISTOR VALUES ARE EXPRESSED IN OHMS, 1/8W 1%
   UNLESS OTHERWISE SPECIFIED.

2. CAPACITOR VALUES ARE EXPRESSED IN MICROFARADS
   UNLESS OTHERWISE SPECIFIED.

DISPLAY
INTERFACE
SCHEMATIC
99400831

CLINITEK 500   11.5

STRIP DETECTOR
SCHEMATIC
99400845

CLINITEK 500   11.7

NOTES:

1. ALL RESISTOR VALUES ARE EXPRESSED IN OHMS, 1/8W 5% UNLESS OTHERWISE NOTED.

2. ALL CAPACITOR VALUES ARE EXPRESSED IN MICROFARADS UNLESS OTHERWISE NOTED.

REF DES USED	REF DES NOT USED
C14	
DS5	
P2	
Q5	
R22	
U4	

MOTHER BOARD SCHEMATIC 99400832

RS232 J6
RXD 3
CTS 5
DSR 6
TXD 2
RTS 4
DTR 8
SIG GND 7
CHASSIS 1

MAX1489E U1
MAX1489E U1
MAX1489E U1
MAX1488E U3
MAX1488E U3
MAX1488E U3

J2 26 32 30 29 28 25 24 23 31 27
J1 1 2 3 4 5 6 7 8 9 10 11 12 32 31

TO MAIN BD.

J2 13 14 15 16 17 18 19 3
C6 1 C7 1 C8 1 C9 1
+5V +12V +12V -12V

RS232 P4
NC 16
RXD 3
NC 17
CTS 5
NC 18
DSR 6
NC 19
NC 21
RTS 4
NC 22
NC 23
TXD 2
NC 24
NC 25
DTR 20
NC 8
NC 9
NC 10
NC 11
NC 12
NC 13
SIG GND 7
CHASSIS 1
NC 14
NC 15

MAX1489E U2
MAX1489E U2
MAX1489E U2
MAX1488E U4
MAX1488E U4
MAX1488E U4
MAX1488E U3

D24 5.6V D23 5.6V D22 5.6V

J3 CENTRONICS
11 BUSY
12 PAPEROUT
1 STROBE
9 DATA8
8 DATA7
7 DATA6
6 DATA5
5 DATA4
4 DATA3
3 DATA2
2 DATA1
16 NC
10 NC
13 NC
14 NC
15 NC
17 NC
18 GND
19 GND
20 GND
21 GND
22 GND
23 GND
24 GND
25 GND

D21 5.6V D20 5.6V D19 5.6V D18 5.6V D17 5.6V D16 5.6V D15 5.6V D14 5.6V

BARCODE J5
6
7
XMIT 5
NC 2
NC 3
REC 4
1

RXE030 F1 +5V
RXE030 F2 +12V
C17 1 C18 1
MAX1489E U2
MAX1488E U4

PRINTER P7
1
2
3
+5V
MAX1489E U1

STRIP DET. P8
1
3
2
4
5
+12V
-12V

POWER SUPPLY P12
6
4
5
2
3
1
+12V
+5V
C19 1 R1 20 3 WATT C20 1
C21 .1 DGND -12V

SHUTTER
DO NOT INSTALL SHUTTER DRIVE COMPONENTS
R14 100 1W R15 100 1W +5V
Q1 IRLL014N
C28 10,000 uf C27 10,000 uf
D13 IN 5400
P6 1 2

HIGHEST REF. DES. USED / REF. DES. NOT USED
P16 / P1
J6 / P2
U7 / P3
D24 / P5
C28 / J4
R19 / C5
F2 / R3
Q1

J1 23 24 25 26 27 28 29 30

NOTES:
1. RESISTOR VALUES ARE EXPRESSED IN OHMS, 1/8W, 1% UNLESS OTHERWISE SPECIFIED.
2. CAPACITOR VALUES ARE EXPRESSED IN MICROFARADS UNLESS OTHERWISE SPECIFIED.

J1 14 15 16 17
J2 4 1 2 8 5 9 11 10

+5V +12V
C22 1
R17 10K
U5 UCN5804B
2 K1 VCC 16
7 K2
11 STEP OUT_A 8
15 OE OUT_B 1
14 DIR OUT_C 6
10 HALF OUT_D 3
9 1_PH
4 GND1 GND3 12
5 GND2 GND4 13
SK13 SK13 SK13 SK13
D1 D2 D3 D4

C3 68uF 25V TANTALUM
+5V +12V
C10 1 C11 1
R4 5 OHM, 3W
R5 5 OHM, 3W
P13
6
5
4
3
2
1
WALKING BEAM MOTOR

+5V +12V
C23 1
R18 10K
U6 UCN5804B
2 K1 VCC 16
7 K2
11 STEP OUT_A 8
15 OE OUT_B 1
14 DIR OUT_C 6
10 HALF OUT_D 3
9 1_PH
4 GND1 GND3 12
5 GND2 GND4 13
SK13 SK13 SK13 SK13
D5 D6 D7 D8

C4 68uF 25V TANTALUM
+5V +12V
C12 1 C13 1
R6 5 OHM, 3W
R7 5 OHM, 3W
P14
6
5
4
3
2
1
PUSHARM MOTOR

+5V +12V
C1 1
R19 10K
U7 UCN5804B
2 K1 VCC 16
7 K2
11 STEP OUT_A 8
15 OE OUT_B 1
14 DIR OUT_C 6
10 HALF OUT_D 3
9 1_PH
4 GND1 GND3 12
5 GND2 GND4 13
SK13 SK13 SK13 SK13
D9 D10 D11 D12

C15 1 +5V C14 1
C2 68uF 25V TANTALUM
P15
6
5
4
3
2
1
READHEAD DRIVE MOTOR

+5V
R8 R11 160 R10 10K
C26 1
P9
4 3 2 1
PUSHARM INTER.

+5V
R9 10K R12 160
C25 1
P10
4 3 2 1
TABLE INTER.

+5V
R10 10K R13 160
C24 1
P11
4 3 2 1
WALKING BEAM INTER.

+5V
R2 10K R16 160
C16 1
P16
4 3 2 1
SHUTTER INTER.
DO NOT INSTALL SHUTTER INTERRUPTER COMPONENTS

CLINITEK 500   11.9

PROCESSOR
SCHEMATIC
PART 1
99400833

NOTES:
1. RESISTOR VALUES ARE EXPRESSED IN OHMS 1/8W 1% UNLESS OTHERWISE NOTED.
2. CAPACITOR VALUES ARE EXPRESSED IN MICROFARADS UNLESS OTHERWISE NOTED.

HIGHEST REF DES USED	REF DES NOT USED
C71	C21,C22,C44,C51
FB13	
J6	
LS1	
P4	
Q2	
R23	
U29	
Y3	

CLINITEK 500   11.11

PROCESSOR SCHEMATIC PART 2 99400833

DISPLAY INTERFACE CONNECTOR

UNUSED GATES

68 PIN PCMCIA CONNECTOR

CLINITEK 500   11.13

PREAMP A/D
BOARD
SCHEMATIC
99400876

NOTES:

1. CAPACITOR VALUES ARE EXPRESSED IN MICROFARADS UNLESS OTHERWISE SPECIFIED.

2. RESISTOR VALUES ARE EXPRESSED IN OHMS, 1% 1/8W UNLESS OTHERWISE SPECIFIED.

HIGHEST REF. DES. USED	HIGHEST REF. DES. NOT USED
C20 P5 U1 VR4 R2	

CLINITEK 500   11.15

INTERCONNECT

CLINITEK 500 11.17

CHAPTER TWELVE – RELEASE TESTING   *Return*

12-0   Introduction

This section describes cleaning and release test procedures that must be performed prior to releasing any CLINITEK 500 instrument back to a customer or into a branch's Customer Service instrument exchange pool. These procedures must be followed for all systems processed by Bayer Diagnostics Customer Service even if no repair was actually made.

12-1   Cleaning and Inspection

Reference

CLINITEK 500 Operating Manual, Section 5 "CARE OF THE INSTRUMENT" for cleaning instructions.   top of chapter

CAUTION

Prior to release of any system, carefully inspect to insure that; cables are routed properly, connectors are secure, no missing or loose screws and that there are no sharp edges on the outer case. Inspect the system for cleanliness and/or cosmetic defects and replace or clean system components as necessary. Particular attention should be paid to components which may have become stained as a result of repeated contact with reagent (i.e. strip sweep or fixed table assembly).

12-2 Exercise All Motions

Reference section 7-3-3-2.

Procedure

1. With the instrument power turned OFF, insert the Instrument PCMCIA Card.

2. Turn the instrument power ON and allow the system to start normally.

3. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

4. Select "EXERCISE ALL MOTIONS" from the menu.

5. Select "10 CYCLES".

6. If all 10 cycles do not pass, an error message will appear. **top of chapter**

12-3 Test Serial Ports

Reference section 7-3-4-1.

12-3-1   Computer Port

Test Equipment required:

- Computer Port Loop Back Connector (p/n 71500555)

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST SERIAL PORTS".

5. Install Loop-back connector on the serial post.

6. Select "COMPUTER PORT".

7. Will indicate PASSED if working properly.

12-3-2   Bar Code Reader Port

Test Equipment required:

- Bar Code Reader Loop Back Connector (p/n 71647007)

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST SERIAL PORTS".

5. Install Loop-back connector.

6. Select "BAR CODE READER PORT".

7. Will indicate PASSED if working properly. top of chapter

12-3-3   Auxiliary Port

Test Equipment required:
- Auxiliary Loop Back Connector (p/n 71647006)

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST SERIAL PORTS".

5. Install Loop-back connector.

6. Select "AUXILIARY PORT".

7. The instrument will indicate PASSED if working properly.   top of chapter

12-4 Printer

Reference section 7-3-4-2.

12-4-1   Instrument Printer

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST PRINTERS".

5. From the "TEST PRINTERS" menu, select "INSTRUMENT PRINTER TEST".

6. The following pattern should print:

   (0123456789)

7. CAPS small letters. ▲▼

12-4-2   External Printer

Test Equipment required:
- Printer with parallel interface

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST PRINTERS".

5. Connect a printer to the parallel port.

6. From the "TEST PRINTERS" menu, select "EXTERNAL PRINTER TEST".

7. The following pattern should print:

   (0123456789) CAPITAL LETTERS, small letters.

12-4-3   Printer Interface PCB Dip Switch Settings

The diagrams bellow indicate Dip switch setting for each switch position

SW1   off / on   ↓↓↑↑↓↓↓↓   8 ... 1

SW2   off / on   ↑↑↑↑↑↑↑↑   8

SW3   off / on   ↑↓↓↓   4 ... 1

NOTE

When the PCB is installed on the electronics bracket the "ON" position of the DIP switches is in the "Down" position. The switch settings are as follows.

1=On, 0=Off

Switch	position 1 2 3 4 5 6 7 8
SW1	1 1 1 1 0 0 1 1
SW2	0 0 0 0 0 0 0 0
SW3	1 1 1 0

12-5   Test Touch Screen

Reference section 7-3-4-3.

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu select "TEST TOUCH SCREEN".

5. Using your finger, push anyplace on the display. An "x" should appear directly under your finger.

6. To exit, push the arrow in the upper right corner. It will step you back to the Main Menu.   top of chapter

12-6   Test Display

Reference section 7-3-4-5.

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "TEST DISPLAY".

5. All pixels must be highlighted.

6. To exit, push the arrow in the upper right corner. It will step you back to the Main Menu.   top of chapter

12-7   Cycle Readheads

Reference section 7-3-6-1.

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "LEVEL 3 TESTS". This will advance you to "Instrument Tests, Level 3" menu.

5. From the "Instrument Tests, Level 3" menu, select "LEVEL 4 TESTS". This will advance you to "Instrument Tests, Level 4" menu.

6. Select "CYCLE READHEADS" from the "Instrument Tests, Level 4" menu.

7. If an error code is not displayed the test passed.

8. To exit, push the arrow in the upper right corner. It will step you back to the Main Menu.   top of chapter

12-8   Strip Detector Test

Reference section 7-3-4-4.

Test Equipment required:
- Multistix10 SG Reagent Strips

Procedure

1. Select Test Strip Detector function from Level 2 menu.

2. Place a strip (Multistix10 SG Reagent Strip) on the fixed table. When the instrument detects a strip it outputs a 'beep'.

3. Move the strip over the Fixed Table covering all the valid strip placement positions. These are between the Pusher Bar and the hood of the upper case which covers the readheads. Keep the end of the strip (last pad) inside the rear rib on the platform.

4. Visually verify that 4 LED's are flashing.

Note

On early units, a 5th LED on the far left may be present but disabled.

5. Press Print Detector Setup Values. Inspect the printout and confirm that the values are between '10' and '254'.

6. If '0' or '255' are reported, then a failure should be recorded and the system needs to be rejected and returned for troubleshooting. top of chapter

12-9   Cycle Table

Reference section 7-3-6-2.

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "LEVEL 3 TESTS". This will advance you to "Instrument Tests, Level 3" menu.

5. From the "Instrument Tests, Level 3" menu, select "LEVEL 4 TESTS". This will advance you to "Instrument Tests, Level 4" menu.

6. Select "CYCLE TABLE" from the "Instrument Tests, Level 4" menu.

7. If an error code is not displayed, the test passed.

8. To exit, push the arrow in the upper right corner. It will step you back to the Main Menu.   top of chapter

12-10 Cycle Blotter

Reference section 7-3-6-3.

Procedure

1. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. From the "Instrument Tests, Level 1" menu, select "LEVEL 2 TESTS". This will advance you to "Instrument Tests, Level 2" menu.

4. From the "Instrument Tests, Level 2" menu, select "LEVEL 3 TESTS". This will advance you to "Instrument Tests, Level 3" menu.

5. From the "Instrument Tests, Level 3" menu, select "LEVEL 4 TESTS". This will advance you to "Instrument Tests, Level 4" menu.

6. Select "CYCLE BLOTTER" from the "Instrument Tests, Level 4" menu.

7. If an error codes is not displayed the test passed.

8. To exit, push the arrow in the upper right corner. It will step you back to the Main Menu.   *top of chapter*

12-11 Setup Strip Centering

Equipment required:
  - Floating Table Hold-down (p/n 71647013)
  - Hard Standard Strip (p/n 95002262)
      Referance section 7-3-3-4

Procedure

1. Install the "Floating Rail Hold-down onto the Fixed table and install the Fixed table onto the instrument.

2. Insert the Instrument Test Card. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test Card. Turn the instrument power ON and allow the system to start normally.

3. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

4. Select the "SETUP STRIP CENTERING" test. The screen will display the current "Strip Centering" value stored in the instrument memory.

5. Place the Hard Standard strip onto the load zone of the fixed table and select the "OK" key. The instrument will then advance the strip under the readheads and calculate a new "Strip Centering " value and store it in the instrument memory. The acceptable range is 4 to 40.   top of chapter

12-12 Strip Walk Test

Reference section 7-3-3-6.

Procedure

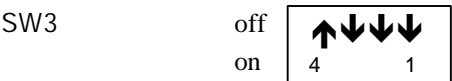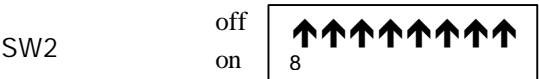1. Insert the Instrument PCMCIA Card. If not already in this condition, with the instrument power turned OFF, Insert the Instrument Test PCMCIA Card. Turn the instrument power ON and allow the system to start normally.

2. From the Main Menu, select "INSTRUMENT TEST". This will advance you to "Instrument Tests, Level 1" menu.

3. Select "STRIP WALK TEST" from the "Instrument Tests, Level 1" menu.

4. The instrument prompts the user to prepare to load 10 strips on to the load zone of the fixed table.

5. Once the "O.K." key is pressed, the instrument starts the test, as each strip is placed on the load zone of the fixed table the pusher arm is activated and moves the strip to the moving table.

6. As the strips are moved under each readhead, the strip tip is located and stored in memory. After all ten strips have had the tip locations checked by both readheads the data is analyzed.

7. A print out of the data and test results is printed out on the internal printer (see figure 7-3-1). Refer to section 7-3-3-6 to determine if the instrument passes the test. top of chapter

In case of a system failing this test, the Drive Housing assembly will require replacement.

12-13 Lubrication

Procedure
1. Clean the Pusher Bar Slide Arm Shaft with alcohol.

2. Apply a thin coat of Lubriplate 630-AA Multi-purpose Grease, part number 50336008.

12-14 Instrument Release Test

Reference Section 7-3-3-1.

Material Required:
- 40453255 DB25 to DB9 Null Modem Cable
- SR00169X Release Test Software
- SR00170X Release Test Limits
- SR00081X Instrument Test PCMCIA Card
- 95002262 Hard Stardard Test Strip
- IBM-PC Compatible computer. Minimum Configuration of 486, 33MHz, 8 Meg Memory running Microsoft Windows 3.1 or Microsoft Windows 95
- Referance Appendix A for software installation and operation.
- Refer to the recommended spare part list (RSL) 024E6470 for current part numbers and fixtures

The Instrument Release Test uses a special test strip (part number 95002262) and a PC running the Release test software (part number SR001690 and SR001700) to perform a Quality check on the operation of the instrument. In this test data is output from the instrument and collected by the PC running the release software. Next, the data is analyzed and compared to predefined limits and if, the results are within the limits, the instrument passes the test. A pass or fail will be displayed on the PC screen

The Test strip that is used for the release test has pads in the following positions P4, P9, P10 and P11.

Procedure
1. With the power off, connect the CT 500 serial to the serial from the PC. Install the floating rail Holddown on the Fixed and install the assembly on the instrument.

2. Power the CLINITEK 500 instrument ON and select the Release Test from the menu.

3. Place the test strip onto the reagent load area of the fixed table and push "OK" button.

4. The instrument moves the strip to the first readhead and scans the strip 10 times, doing the normal positioning, calibration, and readhead movement. Only the reflectance results are saved for output.

5. Calibration is then performed on the first calibration chip. During the calibration, the reflectances, light counts, and dark counts are stored.

6. The results from the first readhead are stored as sequence number 001.

7. The strip is then quickly moved second readhead and steps 3 and 4 are repeated and stored as sequence number 002.

8. The results are available after the strip is read at the second readhead and will be output when asked for by a connected computer.

9. The computer screen will display if the instrument pass or fails the test. If it fails, refer to appendix A for details. (Note: It is possible for the test to be failed due to a program version number mismatch. In this case review the detail screen and confirm that all other tests pass, *back lit in green*, and continue the Release testing)

10. If the test is repeated, any results from a previous test are overwritten.

11. The results may also be printed.

12-15 Leukocyte Correction Factor Generation

Equipment Required
- Instrument Test Card (version 1.03 / 1.03 or higher)
- CT500 Calibration Solution (95002503)
- Multistix 10 SG reagent strips (10 strips required for test)
- Urinetek tubes of equivalent
- Test Tube Holder (opitional)
- Paper Towel

Procedure

1. With the Instrument OFF insert the Instrument Test Card in to the system.

2. Turn the instrument power ON.

3. Scroll through the menu options until you reach the "Instrument Tests, Level 4" menu (see below). Select the "Generate LEU Corr Factor menu option.

```
Instrument Tests, Level 4          [⌂]

[▣] CYCLE READHEADS

[▣] CYCLE TABLE

[▣] CYCLE PUSH BAR

[▣] READ STRIP, DUMP DATA

[▣] PRINT TRANSFERRED DATA

[▣] GENERATE LEU CORR. FACTOR
```

4. The first screen displayed in the Leu Correction Factor test is shown below.

```
┌─────────────────────────────────────┐
│                              ┌───┐   │
│ LEU CORRECTION FACTOR: AA    │ ⬆ │   │
│                              └───┘   │
│      ┌──┐                            │
│      │◖█│ GENERATE LEU CORR. FACTOR  │
│      └──┘                            │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
└─────────────────────────────────────┘
```

The variable "AA" indicates the current LEU correction factor stored for the instrument. The correction factor can have value from –99 to +99.

If the Instrument has not previously had a Leu correction Factor generated, the value of "AA" =00 and no sign (+ / -) will be shown.

5. To set a new correction factor press the key "Generate LEU Corr. Factor", which will then display the following screen.

```
┌─────────────────────────────────────┐
│ Use: MULTISTIX 10 SG                 │
│ RUN 10 STRIPS FOR NEW CORRECTION     │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
│                                      │
└─────────────────────────────────────┘
```

6. When the above screen is displayed, the instrument is ready to start having strips placed upon the load zone of the instrument.

Dipping Strips

The bottle of reagent strips must be stored at room temperature (20-30°C/66-86°F) for at least 1 day before the normalization procedure is performed.
All strips for a given instrument must come from the same bottle.
Remove 10 strips from the bottle just prior to dipping and re-cap the bottle.
Fill a suitable tube with enough test (approximately 10 ml) solution to allow all 10 of the reagent pads to be submerged when the strip is dipped.
The test solution can be used for dipping 1o strips, and then fresh solution will be needed.

---

7. Dip strip into the leukocyte negative solution so that all pads are wet and remove immediately. While removing the strip from the tube, drag the edge along the side of the tube to remove excess solution. Immediately "blot" the strip by **touching the edge** to a paper towel. Do not drag the strip across the towel: touch the edge only, as shown below:

NOTE

The "Blotting" of the reagent strip is only required when performing this test.

Customers are to be instructed not to Blot reagent strips when processing Controls or Samples.

The instrument algorithms are optimized to provide accurate and consistent clinical results for reagent strips that are not blotted; thus blotting will adversely effect results.

8. Immediately place the strip on the instrument fixed table. The strip will be detected and pusher bar will move strip to the readhead areas. After the first strip has been detected, the display will change as shown below.

Note

The variable "AAAA" is the sequence number of the strip that is being processed.
The Variable "BBBBBB" is an Error message if an error condition is detected and is report as a normal CLINITEK 500 error code.

```
Use: MULTISTIX 10 SG
RUN 10 STRIPS FOR LEU CORRECTION      ⬆
                                     ABORT



     SEQUENCE #:AAAAA




BBBBBBBBBBBBBBBBBB                    ⬛
                                     STOP
```

9. You may dip another strip and place on the table (steps 4.3-4.6) as the pusher bar can move every 7 seconds. Ten (10) strips must be run for the instrument to be normalized.

10. After placing the 10th strip, the pusher bar will remain at the right so that no additional strips may be run.

Note:

All 10 strips can be dipped in the same tube of leukocyte negative solution.

A bottle of Clontek 500 calibration solution has a shelf life of 1 year at room tempeture.

11. Once all ten strips have been processed, the results are displayed on the screen as shown above. A printout of the data sets and the minimum, maximum, range, and average decode results will automatically be printed after CT500 normalization is complete.

```
LEU Correction Factor                    ⬆

        AVERAGE:   AAA

        MAXIMUM:   BBB

        MINIMUM:   CCC

        RANGE:     DD


```

12. An instrument passes the test provided that the range value for the test is less than or equal to 34.

Note

Instruments that do not pass this requirement should be retested. If the instrument fails a second testing, it requires additional servicing.   top of chapter

12-15.1   MEMORY RESET

Procedure

1. After the instrument has successfully completed the release test and the wet testing the memory will need to be "reset". This is accomplished by selecting the "SETUP" option from the ready run screen.

```
Use: AAAAAAAAAAAAAAAA
Place Strip.



   SEQUENCE #:BBBBB

   PRINT SETUP

   SETUP


   INSTRUMENT TEST
```

2. After "SETUP" is selected, the following screen will be displayed. From this screen, select the "CLEAR MEMORY" option.

```
SELECT ITEM TO SPECIFY ITS          ⬆
OPTION

 Set the Date AA-BB-CC (M-D-Y)

 Set the Time DD:EE (24 hr)

 Clear Memory

 Printer: FFF

 Strip Type: GGGGGGGGGGGGGGGGGG
```

3. Once the "CLEAR MEMORY" option has been selected, the following screen will display

```
Clear all results from
the CLINITEK memory ?
Are you sure ?

   YES


   NO


   Reset System Memory
```

4. From this screen, select the "Reset System Memory" option. This will erase all results from memory and reset the fixed memory locations to the default values.   top of chapter

12-17 CONFIRM CONFIGURATION

If returning original system to customer, make sure that the customer supplied User Software PCMCIA card is included with the system

---
Note:

If updating the system to a new version of software and it is necessary to maintain customer setup parameters us the following procedure to insure that the customer setup parameters originally in the system have been restored.

1. Install the customer original program card and turn on the instrument. When the instrument prompts to use the setup stored on the program card or stored in instrument memory chose "Stored on Program Card"

2. After the instrument has returned to the ready run screen turn the power off

3. Remove the original program card and install the "New Version of the Customer Program Card".

4. Turn the instrument power back on. When the instrument prompts to use the setup stored on the program card or stored in instrument memory, this time choose instrument memory.

5. After the instrument returns to the ready run screen press the up arrow in the upper right hand corner of the screen to save the set up to the program card

---
Note

If placing the system in Customer Service Exchange Pool, make sure that the latest User Software PCMCIA card is included with the system.   top of chapter

CLINITEKÒ 500 RELEASE TEST LOG

DATE:_____/_____/_____ S/N:_____

A. Cosmetic Inspection and Cleaning ---❏

B. Exercise All Motions--❏

C. Test Serial Ports

    1.   Computer Port   ❏

    2.   Bar Code Reader Port --❏

    3.   Auxiliary Port ---❏

D. Printer

    1.   Instrument Printer ---❏

    2.   External Printer --❏

E. Test Touch Screen --❏

F. Test Display --❏

G. Cycle Readheads ---❏

H. Test Strip Detector---❏

I. Cycle Table ---❏

J. Cycle Blotter--❏

K. Set Strip Centering ---❏

L. Strip Walk Test ---❏

M. Lubrication ---❏

N. Service release Test ---❏

O. LEU Correction Factor=_____ --❏

P. Reset Memory ---❏

Q. Confirm Software Configuration---❏

       Software Version _____

Performed By: _____   Date: _____

Release Approval: _____   Date: _____

Appendix A-CLINITEK 500 Instrument Release Test Data Collection Software *Return*

A-0   Introduction

This appendix will address installing and using the Data Collection Software with the CLINITEK 500 instrument.

Performing the Release Test requires the use of Instrument Test Card and a special data collection program (p/n SR00169A) that will analyze the data from the CLINITEK 500 instrument. This software is supplied in two parts: First is a CD-ROM, which contains the actual data collection program and a "Set-up" program for installing the software onto a PC. The second part is a floppy disk, which contains the "Limits Files" (p/n SR00170A) that are used to determine if data collected from the CLINITEK 500 instrument under test meets the release requirements.

A-1 Software Installation

A-1-1 Hardware Requirements

The following is a listing of Hardware Requirements

        PC configured as follows
                Processor 486 66Mhz (minimum requirement)
                RAM Memory: recommend 16 Meg (8 Meg minimum)
                An available serial port
                Hard Drive with 20 free space
                CD ROM drive
                3.5 inch Floppy disk drive
        Operating system:
                Windows 3.11 or Windows 95

        Null modem serial cable (CLINITEK 500 Service fixture part number 40453255)

A-1-2 Software Installation Guide

A-1-2-1   Windows 3.1 installation

1.   Turn the PC on and allow it to run its normal start-up sequence.

2.   Insert the CD Disk containing the data collection software into the CD-ROM drive.

3.   Select the **File** and then Select **Run** from the drop down menu that will appear.

4.   From the Run option select **Browse** and select the drive letter appropriate for the CD-ROM drive. Choose the "**Setup.exe**" file from the choices displayed and enter **O.K**.

5.   Enter "**O.K.**" to Run "Setup.exe." At this point, the software will create a directory self install the programs.

6.   After the program has been installed onto the hard drive the limits files will need to be copied into the same directory as the program. Once this has been completed, the program will be ready to be used.

A-1-2-2   Windows 95 installation

1. Turn the PC on and allow it to run its normal start-up sequence.

2. Insert the CD Disk containing the data collection software into the CD-ROM drive.

3. Select the **Start box** and then Select **Run** from the drop down menu that will appear.

4. From the Run option select **Browse** and select the drive letter appropriate for the CD-ROM drive. Choose the "**Setup.exe**" file from the choices displayed and enter **O.K**.

5. Enter "**O.K.**" to Run "Setup.exe". At this point, the software will create a directory self install the programs.

6. After the program has been install onto the hard drive the limits files will need to be copied into the same directory as the program. Once this has been completed, the program will be ready to be used.

7.

A-2   Operation of Software

1.   In Windows 3.1 double click on the CT500 program icon. For Windows 95, select the Start button and then Programs. When the program menu slides out click on the CT500 program. This will start the program

2.   When the program starts a screen will appear requiring the following information to be entered:

     Employee ID **000000**

     Procedure #= **4099**

     Test Procedure Revision Level=05

3.   After the log on codes are entered the following screen will be displayed. To run the program select the Run button

4. To perform the Instrument Release Test on a CLINITEK 500 instrument:

5. With the instrument power "Off", install the Instrument Test Card" and connect the serial cable from the computer to the DB25 RS232 serial port on the CLINITEK 500 instrument.

6. Turn the instrument power on. After it has completed the self test and is displaying the screen below select the "**Instrument Test**" option

```
Use: AAAAAAAAAAAAAAA
Place Strip.




[◉]  SEQUENCE #:BBBBB

[◉]  PRINT SETUP

[◉]  SETUP


[◉]  INSTRUMENT TEST
```

7. After selecting the "**Instrument Test** " option the screen below will by displayed. From this screen select the option of "**Instrument Release Test"**

```
Instrument Tests, Level 1                    [⬆]

[◉]  INSTRUMENT RELEASE TEST

[◉]  EXERCISE ALL MOTIONS

[◉]  SENSOR STATUS

[◉]  SETUP STRIP CENTERING
                                   REBOOT [◉]
[◉]  STRIP WALK TEST               SYSTEM

[◉]  LEVEL 2 TESTS
```

8. The screen below will be displayed on the PC. The model number 6470 followed by the instrument serial number needs to be entered into the Model Serial Number field (example: **6470-1000310**)

9. The screen will change to below if the Product Code and Serial Number are entered correctly

10. Move the cursor to the "Mode" button and click on it. Make sure that "Raw Data", ADF" and "Test Results" are all switched to "OFF". This can be verified by see that the bottom of the screen has these options highlighted in red.

11. Move the cursor to the "test" button. A drop down menu will appear. Select the "Start Session" Option.

12. On the CLINITEK 500 instrument place a hard standards test strip on the fixed table and press the begin test key.

13. If the computer and the CLINITEK 500 instrument are set up correctly, you will see the "**Communications Status**" indicator toggling between "**Idle**" and "**Active**". Additionally the "**Hard Standard Results Port 2**" will display "**Pending**" (See screen below). It will take several minutes for the testing to complete depending upon the processor speed of the PC that is running the data collection software.

14. When all of the data has been analyzed the "Hard Standard Results Port 2" will change color from yellow to green and "Pending" will change to "Pass". At this point the CLINITEK 500 instrument can have its power turned off and be disconnected from the PC.

15. If the data has been analyzed and fails the test the Hard Standard Results Port 2" will change color from yellow to red and "Pending" will change to "FAIL" (see screen Below)

16. Selecting "View Results" will display the following Screen.

17. In case of a failure it will be necessary to troubleshoot, identify and correct the problem before re-testing.

A-3   Troubleshooting

In case of an Instrument failing the Instrument Release Test the "View Results" screen can be used as a troubleshooting aid. The test that failed will be in Red>

CT500 Performance Data								
Limits Revision: 02.11						Run Date: 10/26/98		
Instrument Version: X1.30/01.00		6470-1000310				Start Time: 4:04:35 PM		
Description	Read Head #1				Read Head #2			
	IR	Red	Green	Blue	IR	Red	Green	Blue
Signal	1092	1023	1086	913	1497	1359	1419	1439
Offset	187	192	177	194	200	200	178	190
Maximum Count	1279	1215	1263	1107	1697	1559	1597	1629
Filter Placement	72.84	12.12	26.43	9.14	72.54	12.33	25.67	10.55
Out of Band Leakage			10.23				9.37	
Pad 4 Accuracy	73.2	71.93	71.23	65.73	70.53	71.94	69.75	65.66
Pad 4 Precision	0.16	0.23	0.11	0.13	0.07	0.05	0.12	0.08
Pad 10 Accuracy	72.43	71.86	70.89	65.63	70.65	71.82	69.48	65.17
Pad 10 Precision	0.07	0.24	0.11	0.13	0.08	0.09	0.09	0.11
Precision	0.09	0.1	0.13	0.12	0.13	0.13	0.16	0.18

OK

A-3-1 Signal, Offset and Maximum Count Limits

The data that is used in generating values of Signal, Offset, and Maximum Count are readings taken from the Cal Chip.

> The limit for the "**Signal**" is: signal > 600
>
> The limit for the "**Offset**" is: 1< Offset < 399   (A result of 0 or >400 indicates a Preamp failure.)
>
> The limit for the "**Maximum Count**" is: maximum count < 2048.

A-3-2 Filter Placement and Out of Band Leakage

The next two tests "Filter Placement" and "Out of Band Leakage" are testes that verify the operation of the "Quad Detector" which contains the optical filters and optical detectors. The "Filter Placement" test takes readings from the "Blue" pad on the hard standard test strip using the IR, Red and Green channels. The Out of Band Leakage" test takes reading from the "Red" pad on the hard standard test strip using the Green and IR channels These value reported are in percent reflectance (%R). If either of these test fail it is recommended to rerun the test with a "New Hard Standard." If fails a second time the Preamp PCB should be replaced.

If the Instrument "passes" when tested with a new Hard Standard test strip it indicates that the strip, which failed the test, has been damaged. Discard the damaged strip.

A-3-3 Accuracy Pad 4 and Pad 10

Failure of these tests indicates that the Cal Chip on the Fixed Table is not in the proper position (incorrect height of angle). Retest the instrument using a different fixed table, if the error remains it could indicate a problem with the mounting of the table.

A-3-4 Precision Pad 4 and Pad 10

If either of these tests fail, repeat the test a second time with a New Hard Standard test strip. If the error remains it indicates that the lamp may be dirty (clean with alcohol and air dry) or the A/D PCB is not operating correctly (replace A/D PCB)

APPENDIX A

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Appendix B- Hard Standards Maintenance   *Return*

B-1   Introduction

The servicing of the CLINITEK 500 instrument requires the use of "Hard Standard Strips" which are obtained in bottles of five, under the part number95002262, from the Bayer service inventory. These strips are designed to be use for not more than 30 days at which time they should then be discarded. Calibration is not required.

B-2   Storage

B-2-1 Unused Hard Standard Test Strips

New unused Hard Standard Strips should be stored in the labeled container that they came in.

B-2-2 Hard Standard Strips in use

When a Hard Standard Strip has been removed from its original labeled container to be used in the testing of CLINITEK 500 instruments, it should be marked on the handle end of the strip with the start date of its use. During the 30-day period that it will be used it must be segregated from the unused test strips. The container that is used for this segregation should protect the strip from air born contamination and direct light.

B-3   Use of the Test Strip

The test strips have a use life of 30 days. If in that period a strip starts failing instruments a new strip should be used a confirmatory test. If the instrument passes with the new strip, it is likely that the older test strip has been damaged. Damaged strips should be disposed of.

Each day a test strip is used it will be examined every day for signs of damage and dirt if present replace the strip.

B-4   Log sheet of use

It is recommended that a log be kept for the use of the test strips an example of a suitable Log is bellow:

Start date of Strip	Strip ID number	Checked for physical damage and dirt

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APPENDIX C - CLINITEK 200 Emulation Output Format Support   *Return*

Communication Parameters:

Start Bits:	1
Data Bits/Parity	7/Even
	7/Odd
	8/None
Stop Bits:	2
Baud Rate:	1200
	2400
	4800
	9600
	19200
Checksum:	ON
	OFF
Handshake:	ON
	OFF

Hardware Handshake

In order to transmit a character both the "DSR" and "CTS" lines must be high. The instrument will raise the "DTR" line whenever it is ON and will raise the "RTS" line when it is ready to receive or send a character.

Software Handshake

"XON" (DC1 11H or DC2 12H) and "XOFF" (DC3, 13H) protocol is observed. Before any character is transmitted, the input buffer is checked and if a "XOFF" was received, no transmission can occur until an "XON" is received. When the instrument is turned on, "XON" is in effect.

If the Computer Handshake option is set to ON, the instrument responds to the reception of the following control characters as follows: (All other characters are ignored.)

- "Prompt" (DC1 or optionally a DC2). (11H or 12H) A "Prompt" causes the instrument to transmit the presently addressed set of data. (Data for one test strip.)

- A prompt received after an XOFF has been received is also treated as an XON.

- Any prompt received while data is being transmitted is ignored.

- A prompt received when there is no data available to send is saved, causing the next set of data to be transmitted when available.

- "ACK" (06H) confirms the receipt of the data set by the computer and causes the instrument to address the next available set of data. Any additional ACK is ignored until a Prompt to send the next data set is received. (i.e., Data sets may not be "skipped".)

- "NAK" (15H) causes no action to be taken so that the last set of data is transmitted again when the next Prompt is received. Since this is the default condition, the NAK need not be sent to the instrument. (i.e., After a set of data is transmitted, if another prompt is received the same set of data is retransmitted.)

Computer Port Connections (Serial RS-232)

Pin #	Signal Name	Function	Signal Source
1	chas gnd	protective ground	N/A
2	TXD	transmitted data	CLINITEK 200
3	RXD	received data	computer (note 1)
4	RTS	request to send	CLINITEK 200 (note 2)
5	CTS	clear to send	computer (note 3)
6	DSR	data set ready	computer (note 4)
7	sig. gnd	signal ground	N/A
20	DTR	data terminal ready	CLINITEK 200 (note 5)

(All other pins are unused.)

NOTES:
1. Received data: Used only to input control characters for handshake.

2. Request to send: This output indicates to the computer that it may send a control character.

3. Clear to send: This input is checked before sending each character and if high (ie. positive), the next character is sent. If not supplied by the computer, pin 5 must be jumpered to pin 20.

4. Data set ready: The computer must raise this line (apply a positive voltage) whenever it is ready to receive data. If not supplied by the computer, pin 6 must be jumpered to pin 20.

5. Data terminal ready: This output is high (positive) when the instrument is on.

6. All RS-232 signal lines not shown above are NOT implemented.

Data Set Information
- Each data set consists of 246 characters (248 characters if the Computer Checksum option is set to ON). A data set contains the results for one test strip.

- An "STX" is output as the first character of each set.

- If the Computer Checksum option is set to ON, a checksum of all bytes sent between the STX and ETX is obtained and truncated to 8 bits. This is sent as two hexadecimal digits 0 thru F, the most significant four bits first. These two ASCII characters are sent preceding the ETX.

- An "ETX" is output as the last character of each set.

Data Set Output Format

```
stxcrlf                          (3 characters)
#A-AAA••••••BB-BB-BBcrlf (22 characters)   (25 characters total)
GLU•HHHHHHHHHHHHHHHHcrlf(22 characters)    (47 characters total)
BIL•HHHHHHHHHHHHHHHHcrlf(22 characters)    (69 characters total)
CCC•HHHHHHHHHHHHHHHHcrlf(22 characters)    (91 characters total)
DDD•HHHHHHHHHHHHHHHHcrlf(22 characters)    (113 characters total)
EEE•HHHHHHHHHHHHHHHHcrlf(22 characters)    (135 characters total)
pH••HHHHHHHHHHHHHHHHcrlf (22 characters)   (157 characters total)
PRO•HHHHHHHHHHHHHHHHcrlf(22 characters)    (179 characters total)
FFF•HHHHHHHHHHHHHHHHcrlf(22 characters)    (201 characters total)
NIT•HHHHHHHHHHHHHHHHcrlf(22 characters)    (223 characters total)
GGG•HHHHHHHHHHHHHHHHcrlf(22 characters)    (245 characters total)
etx                            (1 character)        (246 characters total)
OR
ck1ck2etx                      (3 characters)       (248 characters total)
```

Variables:

•:	Represents a space.
stx:	START OF TEXT character (02H, 3).
ck1:	upper 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
ck2:	lower 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
etx:	END OF TEXT character (03H,).
cr:	Represents the carriage return character (0DH, ^M).
lf:	Represents the line feed character (0AH, ^J).
A-AAA:	Represents the SEQ#.
BB-BB-BB:	Represents the date of the test. The date is displayed in the format selected on Screen: Protected Setup (2/8) The date separator is always an endash (-).
CCC:	Represents the language/units dependent test label for Ketone.
DDD:	Represents the language/units dependent test label for SG
EEE:	Represents the language/units dependent test label for Occult Blood.
FFF:	Represents the language/units dependent test label for Urobilinogen
GGG:	Represents the language/units dependent test label. for Leukocyte.
H:	Represents the test result label. This field is right justified. Each test result label contains 16 characters. Character positions not used are filled with spaces.

Example:
```
#0-021    08-13-97
GLU       NEGATIVE
BIL       NEGATIVE
KET       NEGATIVE
SG           1.025
BLO          TRACE
pH             6.5
PRO       NEGATIVE
URO    1.0 E.U./dL
NIT       POSITIVE
LEU          SMALL
```

NOTES:

1. The SEQ # consists of the prefix number and index number. It is created from the CLINITEK 500 SEQ#. Starting from the left of the CLINITEK 500 SEQ#, position 1 is dropped, position 2 becomes the prefix digit, an endash is appended, and then positions 3 through 5 are used as the index portion of the SEQ#.

2. Although the date used with CLINITEK 200 data is the date of data transfer and NOT the date when the strips were run, the date used for CLINITEK 500 output is the date the test was performed.

3. The order of transmission for test results is fixed. It is always:
    GLU, BIL, KET, SG, BLO, pH, URO, NIT, LEU.

4. The test abbreviation is a three character left justified field. For SG and pH, the third character is a space.

5. Positive test results are never marked.

6. Edited test results are never marked.

7. The test result field may be replaced by '..........ERROR' for all tests in a record. The word 'ERROR' is NOT translated.

8. The following data fields are NOT transmitted:
Sample ID
Tech ID
Color
Clarity

Result Value Conversions From CLINITEK® 500 to CLINITEK® 200

English Conventional

Supports CLINITEK® 200 Program Card A40100

English Conventional with PLUS System set to OFF			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200
Glucose (GLU)	NEGATIVE 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIVE 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIVE SMALL MODERATE LARGE	no conversion required	NEGATIVE SMALL MODERATE LARGE
Ketone (KET)	NEGATIVE TRACE 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIVE TRACE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLO)	NEGATIVE TRACE-INTACT TRACE-LYSED SMALL MODERATE LARGE	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE TRACE TRACE SMALL MODERATE LARGE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVE TRACE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE

English Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIVE TRACE SMALL MODERATE LARGE	no conversion required	NEGATIVE TRACE SMALL MODERATE LARGE

Supports CLINITEK® 200 Program Card A40100

English Conventional with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	100 mg/dL
	1+	>>>>>>>>>	250 mg/dL
	2+	>>>>>>>>>	500 mg/dL
	3+	>>>>>>>>>	>=1000 mg/dL
Bilirubin (BIL)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	SMALL
	2+	>>>>>>>>>	MODERATE
	3+	>>>>>>>>>	LARGE
Ketone (KET)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	15 mg/dL
	2+	>>>>>>>>>	40 mg/dL
	3+	>>>>>>>>>	>=80 mg/dL
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (BLO)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE-INTACT	>>>>>>>>>	TRACE
	TRACE-LYSED	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	SMALL
	2+	>>>>>>>>>	MODERATE
	3+	>>>>>>>>>	LARGE
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	30 mg/dL
	2+	>>>>>>>>>	100 mg/dL
	3+	>>>>>>>>>	>=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL		0.2 E.U./dL
	1.0 E.U./dL		1.0 E.U./dL
	2.0 E.U./dL	no conversion required	2.0 E.U./dL
	4.0 E.U./dL		4.0 E.U./dL
	>=8.0 E.U./dL		>=8.0 E.U./dL
Nitrite (NIT)	NEGATIVE	no conversion required	NEGATIVE
	POSITIVE		POSITIVE
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	SMALL
	2+	>>>>>>>>>	MODERATE
	3+	>>>>>>>>>	LARGE

English Nordic

Supports CLINITEK® 200 Program Card C40101

English Nordic with PLUS System set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	TRACE
	2+	>>>>>>>>>	+
	3+	>>>>>>>>>	++
	4+	>>>>>>>>>	+++
Bilirubin (BIL)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Ketone (KET)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	TRACE
	2+	>>>>>>>>>	+
	3+	>>>>>>>>>	++
	4+	>>>>>>>>>	+++
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (BLD)	NEGATIVE	>>>>>>>>>	NEGATIVE
	+/- INTACT	>>>>>>>>>	TRACE
	+/-	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIVE	>>>>>>>>>	NEGATIVE
	+/-	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Urobilinogen (UBG)	3.2 umol/L	>>>>>>>>>	NORMAL
	16 umol/L	>>>>>>>>>	NORMAL
	33 umol/L	>>>>>>>>>	+
	66 umol/L	>>>>>>>>>	++
	>=131 umol/L	>>>>>>>>>	+++
Nitrite (NIT)	NEGATIVE	no conversion required	NEGATIVE
	POSITIVE		POSITIVE

English Nordic with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>>	TRACE
	2+	>>>>>>>>>>	+
	3+	>>>>>>>>>>	++
	4+	>>>>>>>>>>	+++

Supports CLINITEK® 200 Program Card C40103

Test	English Nordic with PLUS System set to ON		
	CLINITEK 500	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Bilirubin (BIL)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Ketone (KET)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (BLD)	NEGATIVE	>>>>>>>>>	NEGATIVE
	+/- INTACT	>>>>>>>>>	TRACE
	+/-	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Urobilinogen (UBG)			
	3.2 umol/L	>>>>>>>>>	NORMAL
	16 umol/L	>>>>>>>>>	NORMAL
	33 umol/L	>>>>>>>>>	+
	66 umol/L	>>>>>>>>>	++
	>=131 umol/L	>>>>>>>>>	+++
Nitrite (NIT)	NEGATIVE	>>>>>>>>>	NEGATIVE
	POSITIVE	>>>>>>>>>	+
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	TRACE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++

English S.I.

Supports CLINITEK® 200 Program Card C40104

English S.I. with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVE 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L	no conversion required	NEGATIVE 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L
Bilirubin (BIL)	NEGATIVE SMALL MODERATE LARGE	no conversion required	NEGATIVE SMALL MODERATE LARGE
Ketone (KET)	NEGATIVE TRACE 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	no conversion required	NEGATIVE TRACE 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLD)	NEGATIVE TRACE-INTACT TRACE-LYSED Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVE TRACE TRACE SMALL MODERATE LARGE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 0.3 g/L 1.0 g/L >=3.0 g/L	no conversion required	NEGATIVE TRACE 0.3 g/L 1.0 g/L >=3.0 g/L
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE

English S.I. with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	Ca 15 Leu/uL	>>>>>>>>>	TRACE
	Ca 70 Leu/uL	>>>>>>>>>	SMALL
	Ca 125 Leu/uL	>>>>>>>>>	MODERATE
	Ca 500 Leu/uL	>>>>>>>>>	LARGE

Supports CLINITEK® 200 Program Card C40102

English S.I. with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	+
	1+	>>>>>>>>>	++
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Bilirubin (BIL)	NEGATIVE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	SMALL
	2+	>>>>>>>>>	MODERATE
	3+	>>>>>>>>>	LARGE
Ketone (KET)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	+
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (BLD)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE-INTACT	>>>>>>>>>	+
	TRACE-LYSED	>>>>>>>>>	+
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++
Urobilinogen (UBG)	3.2 umol/L		3.2 umol/L
	16 umol/L		16 umol/L
	33 umol/L	no conversion required	33 umol/L
	66 umol/L		66 umol/L
	>=131 umol/L		>=131 umol/L
Nitrite (NIT)	NEGATIVE	>>>>>>>>>	NEGATIVE
	POSITIVE	>>>>>>>>>	+
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	TRACE	>>>>>>>>>	+
	1+	>>>>>>>>>	+
	2+	>>>>>>>>>	++
	3+	>>>>>>>>>	+++

French Conventional

Supports CLINITEK® 200 Program Card G40100

	French Conventional with PLUS System set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIF TRACES 2.5 g/L 5.0 g/L >=10.0 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIF FAIBLE MOYEN FORT	no conversion required	NEGATIF FAIBLE MOYEN FORT
Ketone (CET)	NEGATIF TRACES 0.15 g/L 0.4 g/L >=0.8 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSE env. 25 GR/uL env. 80 GR/uL env. 200 GR/uL	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE TRACE FAIBLE MOYEN FORT
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF

French Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIF	>>>>>>>>>	NEGATIF
	env. 15 GB/uL	>>>>>>>>>	Ca 15 cells/uL
	env. 70 GB/uL	>>>>>>>>>	Ca 70 cells/uL
	env. 125 GB/uL	>>>>>>>>>	Ca 125 cells/uL
	env. 500 GB/uL	>>>>>>>>>	Ca 500 cells/uL

APPENDIX C

Supports CLINITEK® 200 Program Card G40100

	French Conventional with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIF 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF FAIBLE MOYEN FORT
Ketone (CET)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE TRACE FAIBLE MOYEN FORT
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF TRACE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF
Leukocytes (LEU)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIF Ca. 15 cells/uL Ca. 70 cells/uL Ca. 125 cells/uL Ca. 500 cells/uL

French S.I.

Support for CLINITEK® 200 Program Card H40100

French S.I. with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIF 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L	no conversion required	NEGATIF 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L
Bilirubin (BIL)	NEGATIF FAIBLE MOYEN FORT	no conversion required	NEGATIF FAIBLE MOYEN FORT
Ketone (CET)	NEGATIF TRACES 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	no conversion required	NEGATIF TRACES 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	**DEN >>>>>>>>> SG** no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSE FAIBLE MOYEN FORT	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF ENV. 10 GR/uL ENV. 10 GR/uL ENV. 25 GR/uL ENV. 80 GR/uL ENV. 200 GR/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L	no conversion required	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L
Urobilinogen (URO)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF

French S.I. with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	ENV. 15 LEU/uL
	FAIBLE	>>>>>>>>>	ENV. 70 LEU/uL
	MOYEN	>>>>>>>>>	ENV. 125 LEU/uL
	FORT	>>>>>>>>>	ENV. 500 LEU/uL

Support for CLINITEK® 200 Program Card H40100

French S.I. with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	5.5 mmol/L
	1+	>>>>>>>>>	14 mmol/L
	2+	>>>>>>>>>	28 mmol/L
	3+	>>>>>>>>>	>=55 mmol/L
Bilirubin (BIL)	NEGATIF	>>>>>>>>>	NEGATIF
	1+	>>>>>>>>>	FAIBLE
	2+	>>>>>>>>>	MOYEN
	3+	>>>>>>>>>	FORT
Ketone (CET)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	TRACES
	1+	>>>>>>>>>	1.5 mmol/L
	2+	>>>>>>>>>	3.9 mmol/L
	3+	>>>>>>>>>	>=7.8 mmol/L
Specific Gravity (DEN)		**DEN >>>>>>>>> SG**	
	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (SNG)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES-INTACT	>>>>>>>>>	ENV. 10 GR/uL
	TRACES-LYSE	>>>>>>>>>	ENV. 10 GR/uL
	1+	>>>>>>>>>	ENV. 25 GR/uL
	2+	>>>>>>>>>	ENV. 80 GR/uL
	3+	>>>>>>>>>	ENV. 200 GR/uL
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	TRACES
	1+	>>>>>>>>>	0.3 g/L
	2+	>>>>>>>>>	1.0 g/L
	3+	>>>>>>>>>	>=3.0 g/L
Urobilinogen (URO)	3.2 umol/L		3.2 umol/L
	16 umol/L		16 umol/L
	33 umol/L	no conversion required	33 umol/L
	66 umol/L		66 umol/L
	>=131 umol/L		>=131 umol/L
Nitrite (NIT)	NEGATIF	no conversion required	NEGATIF
	POSITIF		POSITIF
Leukocytes (LEU)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	ENV. 15 LEU/uL
	1+	>>>>>>>>>	ENV. 70 LEU/uL
	2+	>>>>>>>>>	ENV. 125 LEU/uL
	3+	>>>>>>>>>	ENV. 500 LEU/uL

German Conventional

Supports CLINITEK® 200 Program Card F40100

German Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIV 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIV 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIV SCHWACH MAESSIG STARK	no conversion required	NEGATIV SCHWACH MAESSIG STARK
Ketone (KET)	NEGATIV SPUR 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIV SPUR 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OBL)	0 Ery/uL Ca 10 Ery/uL Ca 10 Ery/uL Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	0 rbc/uL Ca 10 rbc/uL Ca 10 rbc/uL Ca 25 rbc/uL Ca 80 rbc/uL Ca 200 rbc/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIV SPUR 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion needed	NEGATIV SPUR 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (UBG)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	no conversion needed	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIV POSITIV	no conversion needed >>>>>>>>>	NEGATIV POSITIV

German Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	0 Leu/uL	>>>>>>>>>	0 cells/uL
	Ca 15 Leu/uL	>>>>>>>>>	Ca 15 cells/uL
	Ca 70 Leu/uL	>>>>>>>>>	Ca 70 cells/uL
	Ca 125 Leu/uL	>>>>>>>>>	Ca 125 cells/uL
	Ca 500 Leu/uL	>>>>>>>>>	Ca 500 cells/uL

Supports CLINITEK® 200 Program Card F40100

Test	German Conventional with PLUS System set to ON		
	CLINITEK 500	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	100 mg/dL
	1+	>>>>>>>>>	250 mg/dL
	2+	>>>>>>>>>	500 mg/dL
	3+	>>>>>>>>>	>=1000 mg/dL
Bilirubin (BIL)	NEGATIV	>>>>>>>>>	NEGATIV
	1+	>>>>>>>>>	SCHWACH
	2+	>>>>>>>>>	MAESSIG
	3+	>>>>>>>>>	STARK
Ketone (KET)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	SPUR
	1+	>>>>>>>>>	15 mg/dL
	2+	>>>>>>>>>	40 mg/dL
	3+	>>>>>>>>>	>=80 mg/dL
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (OBL)	NEGATIV	>>>>>>>>>	0 rbc/uL
	SPUR-ZELLEN	>>>>>>>>>	Ca 10 rbc/uL
	SPUR-LYSE	>>>>>>>>>	Ca 10 rbc/uL
	1+	>>>>>>>>>	Ca 25 rbc/uL
	2+	>>>>>>>>>	Ca 80 rbc/uL
	3+	>>>>>>>>>	Ca 200 rbc/uL
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	SPUR
	1+	>>>>>>>>>	30 mg/dL
	2+	>>>>>>>>>	100 mg/dL
	3+	>>>>>>>>>	>=300 mg/dL
Urobilinogen (UBG)	0.2 mg/dL	>>>>>>>>>	0.2 mg/dL
	1.0 mg/dL	>>>>>>>>>	1.0 mg/dL
	2.0 mg/dL	>>>>>>>>>	2.0 mg/dL
	4.0 mg/dL	>>>>>>>>>	4.0 mg/dL
	>=8.0 mg/dL	>>>>>>>>>	>=8.0 mg/dL
Nitrite (NIT)	NEGATIV	>>>>>>>>>	NEGATIV
	POSITIV	>>>>>>>>>	POSITIV
Leukocytes (LEU)	NEGATIV	>>>>>>>>>	0 cells/uL
	SPUR	>>>>>>>>>	Ca 15 cells/uL
	1+	>>>>>>>>>	Ca 70 cells/uL
	2+	>>>>>>>>>	Ca 125 cells/uL
	3+	>>>>>>>>>	Ca 500 cells/uL

German S.I.

Supports CLINITEK® 200 Program Card C40104

German S.I. with PLUS System set to OFF			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200
Glucose (GLU)	NEGATIV 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIV 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIV SCHWACH MAESSIG STARK	no conversion required	NEGATIV SCHWACH MAESSIG STARK
Ketone (KET)	NEGATIV SPUR 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIV SPUR 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OBL)	0 Ery/uL Ca 10 Ery/uL Ca 10 Ery/uL Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	0 rbc/uL Ca 10 rbc/uL Ca 10 rbc/uL Ca 25 rbc/uL Ca 80 rbc/uL Ca 200 rbc/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIV SPUR 0.3 g/L 1.0 g/L >=3.0 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIV SPUR 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIV POSITIV	no conversion required	NEGATIV POSITIV

German S.I. with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIV	>>>>>>>>>>	0 cells/uL
	Ca 15 Leu/uL	>>>>>>>>>>	Ca 15 cells/uL
	Ca 70 Leu/uL	>>>>>>>>>>	Ca 70 cells/uL
	Ca 125 Leu/uL	>>>>>>>>>>	Ca 125 cells/uL
	Ca 500 Leu/uL	>>>>>>>>>>	Ca 500 cells/uL

Supports CLINITEK® 200 Program Card C40104

German S.I. with PLUS system set to ON			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200
Glucose (GLU)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	100 mg/dL
	1+	>>>>>>>>>	250 mg/dL
	2+	>>>>>>>>>	500 mg/dL
	3+	>>>>>>>>>	>=1000 mg/dL
Bilirubin (BIL)	NEGATIV	>>>>>>>>>	NEGATIV
	1+	>>>>>>>>>	SCHWACH
	2+	>>>>>>>>>	MAESSIG
	3+	>>>>>>>>>	STARK
Ketone (KET)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	SPUR
	1+	>>>>>>>>>	15 mg/dL
	2+	>>>>>>>>>	40 mg/dL
	3+	>>>>>>>>>	>=80 mg/dL
Specific Gravity (SG)	<= 1.005		<= 1.005
	1.010		1.010
	1.015		1.015
	1.020	no conversion required	1.020
	1.025		1.025
	>=1.030		>=1.030
Blood (OBL)	NEGATIV	>>>>>>>>>	0 rbc/uL
	SPUR-ZELLEN	>>>>>>>>>	Ca 10 rbc/uL
	SPUR-LYSE	>>>>>>>>>	Ca 10 rbc/uL
	1+	>>>>>>>>>	Ca 25 rbc/uL
	2+	>>>>>>>>>	Ca 80 rbc/uL
	3+	>>>>>>>>>	Ca 200 rbc/uL
pH (pH)	5.0		5.0
	5.5		5.5
	6.0		6.0
	6.5		6.5
	7.0	no conversion required	7.0
	7.5		7.5
	8.0		8.0
	8.5		8.5
	>=9.0		>=9.0
Protein (PRO)	NEGATIV	>>>>>>>>>	NEGATIV
	SPUR	>>>>>>>>>	SPUR
	1+	>>>>>>>>>	30 mg/dL
	2+	>>>>>>>>>	100 mg/dL
	3+	>>>>>>>>>	>=300 mg/dL
Urobilinogen (UBG)	3.2 umol/L	>>>>>>>>>	0.2 mg/dL
	16 umol/L	>>>>>>>>>	1.0 mg/dL
	33 umol/L	>>>>>>>>>	2.0 mg/dL
	66 umol/L	>>>>>>>>>	4.0 mg/dL
	>=131 umol/L	>>>>>>>>>	>=8.0 mg/dL
Nitrite (NIT)	NEGATIV	>>>>>>>>>	NEGATIV
	POSITIV	>>>>>>>>>	POSITIV
Leukocytes (LEU)	NEGATIV	>>>>>>>>>	0 cells/uL
	SPUR	>>>>>>>>>	Ca 15 cells/uL
	1+	>>>>>>>>>	Ca 70 cells/uL
	2+	>>>>>>>>>	Ca 125 cells/uL
	3+	>>>>>>>>>	Ca 500 cells/uL

Italian

Supports CLINITEK® 200 Program Card E40100

	Italian with PLUS System set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVO 1.0 g/L 2.5 g/L 5.0 g/L >=10.0 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO 0.1 g/dL 0.25 g/dL 0.50 g/dL >=1.0 g/dL
Bilirubin (BIL)	NEGATIVO LEGGERO MEDIO FORTE	no conversion required	NEGATIVO LEGGERO MEDIO FORTE
Ketone (KET)	NEGATIVO TRACCE 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIVO TRACCE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (PS)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO TRACCE(INT.) TRACCE(LIS.) LEGGERO MEDIO FORTE	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO TRACCE TRACCE LEGGERO MEDIO FORTE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO TRACCE 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVO TRACCE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO

Italian with PLUS System set to OFF			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200
Leukocytes (LEU)	NEGATIVO	>>>>>>>>>>	NEGATIVO
	Ca 15 Cel/uL	>>>>>>>>>>	Ca 15 cells/uL
	Ca 70 Cel/uL	>>>>>>>>>>	Ca 70 cells/uL
	Ca 125 Cel/uL	>>>>>>>>>>	Ca 125 cells/uL
	Ca 500 Cel/uL	>>>>>>>>>>	Ca 500 cells/uL

Supports CLINITEK® 200 Program Card E40100

Italian with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVO TRACCE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO 0.1 g/dL 0.25 g/dL 0.50 g/dL >=1.0 g/dL
Bilirubin (BIL)	NEGATIVO 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO LEGGERO MEDIO FORTE
Ketone (KET)	NEGATIVO TRACCE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO TRACCE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (PS)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO TRACCE(INT.) TRACCE(LIS.) 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO TRACCE TRACCE LEGGERO MEDIO FORTE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO TRACCE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO TRACCE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO
Leukocytes (LEU)	NEGATIVO TRACCE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO Ca 15 cells/uL Ca 70 cells/uL Ca 125 cells/uL Ca 500 cells/uL

Kanji

Supports CLINITEK® 200 Program Card B40101

Kanji with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	- 0.1 g/dL 0.25 g/dL 0.5 g/dL >=1.0 g/dL	no conversion required	- 0.1 g/dL 0.25 g/dL 0.5 g/dL >=1.0 g/dL
Bilirubin (BIL)	- 1+ 2+ 3+	no conversion required	- 1+ 2+ 3+
Ketone (KET)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OB)	- +/-INTACT +/-LYSED 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	- +/- +/- 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	- +/- 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	- +/- 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	- +	no conversion required	- +

Kanji with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (WBC)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+

Supports CLINITEK® 200 Program Card B40101

Kanji with PLUS system set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	- +/- 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	- 0.1 g/dL 0.25 g/dL 0.5 g/dL >=1.0 g/dL
Bilirubin (BIL)	- 1+ 2+ 3+	no conversion required	- 1+ 2+ 3+
Ketone (KET)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OB)	- +/-INTACT +/-LYSED 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	- +/- +/- 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	- +/- 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	- +/- 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	- +	no conversion required	- +
Leukocytes (WBC)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+

Spanish

Supports CLINITEK® 200 Program Card D40100

Spanish with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVO 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIVO 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIVO BAJO MODERADO ALTO	no conversion required	NEGATIVO BAJO MODERADO ALTO
Ketone (CET)	NEGATIVO INDICIOS 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIVO INDICIOS 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO IND.INTACTOS IND.HEMOLIZ. Apr 25 Hem/uL Apr 80 Hem/uL Apr 200 Hem/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO Apro 10 ERI/uL Apro 10 ERI/uL Apro 25 ERI/uL Apro 80 ERI/uL Apro 200 ERI/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO INDICIOS 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVO INDICIOS 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO

	Spanish with PLUS system set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Leukocytes (LEU)	NEGATIVO	>>>>>>>>>	NEGATIVO
	Apr 15 Leu/uL	>>>>>>>>>	Apro 15 cel/uL
	Apr 70 Leu/uL	>>>>>>>>>	Apro 70 cel/uL
	Apr 125 Leu/uL	>>>>>>>>>	Apro 125 cel/uL
	Apr 500 Leu/uL	>>>>>>>>>	Apro 500 cel/uL

Support for CLINITEK® 200 Program Card D40100

Spanish with PLUS system set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200**
Glucose (GLU)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIVO 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO BAJO MODERADO ALTO
Ketone (CET)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIOS 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO IND. INTACTOS IND.HEMOLIZ. 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO Apro 10 ERI/uL Apro 10 ERI/uL Apro 25 ERI/uL Apro 80 ERI/uL Apro 200 ERI/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIOS 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO
Leukocytes (LEU)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO Apro 15 cel/uL Apro 70 cel/uL Apro 125 cel/uL Apro 500 cel/uL

APPENDIX D - CLINITEK 200+ Emulation Output Format Support   *Return*

Communication Parameters

Start Bits:	1
Data Bits/Parity	7/Even
	7/Odd
	8/None
Stop Bits:	2
Baud Rate:	1200
	2400
	4800
	9600
	19200
Checksum:	ON
	OFF
Handshake:	ON
	OFF

Data Control Character Support

<CAN>	Reset the RS-232 port to default condition.
<DC1>, <DC2>	XON, enables transmission.
<DC3>	XOFF, disables transmission.

Hardware Handshake
In order to transmit a character both the "DSR" and "CTS" lines must be high. The instrument will raise the "DTR" line whenever it is ON and will raise the "RTS" line when it is ready to receive or send a character.

Software Handshake
- "XON" (DC1 11H or DC2 12H) and "XOFF" (DC3, 13H) protocol is observed. Before any character is transmitted, the input buffer is checked and if a "XOFF" was received, no transmission can occur until an "XON" is received. When the instrument is turned on, "XON" is in effect.
- If the Computer Handshake option is set to ON, the instrument responds to the reception of the following control characters as follows: (All other characters are ignored.)

- "Prompt" (DC1 or DC2). (11H or 12H) A "Prompt" causes the instrument to transmit the presently addressed set of data. (Data for one test strip.) If an ENQ was the last control character received, the instrument ID message is sent instead.
- If transmission was disabled while sending a data set, a DC1 or DC2 acts only as an XON. If transmission was disabled when a data set was not being sent, a DC1 or DC2 acts both as an XON and as a "Prompt".

- "ACK" (06H) confirms the receipt of the data set by the computer and causes the instrument to address the next available set of data. Any additional ACK is ignored until a Prompt to send the next data set is received. (i.e., Data sets may not be "skipped".)

- "NAK" (15H) causes no action to be taken so that the last set of data is transmitted again when the next Prompt is received. Since this is the default condition, the NAK need not be sent to the instrument. (i.e., After a set of data is transmitted, if another prompt is received the same set of data is retransmitted.)

- "ENQ" (05H) tells the instrument send the instrument ID message when the next DC1 or Dc2 is received.

Computer Port Connections (Serial RS-232)

Pin #	Signal Name	Function	Signal Source
1	chas gnd	protective ground	N/A
2	TXD	transmitted data	CLINITEK 200+
3	RXD	received data	computer
4	RTS	request to send	CLINITEK 200+ (note 1)
5	CTS	clear to send	computer (note 2)
6	DSR	data set ready	computer (note 3)
7	sig. gnd	signal ground	N/A
20	DTR	data terminal ready	CLINITEK 200+ (note 4)

(All other pins are unused.)

NOTES:

1. Request to send: This output indicates to the computer that it may send a control character.

2. Clear to send: This input is checked before sending each character and if high (ie. positive), the next character is sent. If not supplied by the computer, pin 5 may be jumpered to pin 4 or pin 20.

3. Data set ready: The computer must raise this line (apply a positive voltage) whenever it is ready to receive data. If not supplied by the computer, pin 6 may be jumpered to pin 20.

4. Data terminal ready: This output is high (positive) when the instrument is on.

5. The following signal lines are NOT implemented:
    Pin 8:   Received line Signal Detector
    Pin 22:   Ring Indicator line

Instrument ID Message Information

*   The instrument ID message is output to the serial port when an **<ENQ>** (05H) control character is received followed by a **<DC1>** or **<DC2>**.

*   An "STX" is output as the first character of the ID message.

*   If the Computer Checksum option is set to ON, a checksum of all bytes sent between the STX and ETX is obtained and truncated to 8 bits. This is sent as two hexadecimal digits 0 thru F, the most significant four bits first. These two ASCII characters are sent preceding the ETX.

*   An "ETX" is output as the last character of the ID message.

Example:

```
stxcrlf                         (3 characters)
ID•AA:AA•BB-BB-BBcrlf           (17 characters and crlf)
CT200+•••02.04crlf              (14 characters and crlf)
CCCCCCCCCCCCCCCCCCCCcrlf        (20 characters and crlf)
DDDDDDDDDDDDDDDDDDDDcrlf        (20 characters and crlf)
etx                             (1 character)
OR
ck1ck2etx                       (3 characters)
```

Variables:

•:	Represents a space.
stx:	START OF TEXT character (02H, 3).
ck1:	upper 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
ck2:	lower 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
etx:	END OF TEXT character (03H,).
cr:	Represents the carriage return character (0DH, ^M).
lf:	Represents the line feed character (0AH, ^J).
AA:AA:	Represents the time in 24 hour format.
BB-BB-BB:	Represents the date. The date is formatted in the format selected on Screen: Protected Setup (2/8). The date separator is always sent as an endash (-).
C…:	Represents the language/units selection made on. Screen: Protected Setup (1/8)
D…:	Represents the test as selected on Screen: Unprotedted Setup.

Language/Unit Selection Conversion Chart

CLINITEK® 500 Language/Unit Selection	CLINITEK® 200+ Conversion
Language: English Units: Conventional	ENGLISH•-••CONV.
Language: English Units: Nordic	ENGLISH•-••S.I.
Language: English Units: S.I.	ENGLISH•-••S.I.
Language: Francais Units: Conventional	FRENCH•-••CONV.
Language: Francais Units: S.I.	FRENCH•-••S.I.
Language: Deutsch Units: Conventional	GERMAN
Language: Deutsch Units: S.I.	GERMAN
Language: Italiano	ITALIAN
Language: Kanji	ENGLISH•-••+/-
Language: Spanish	SPANISH

Urine Chemistry Test Support Chart

CLINITEK̀ 500 Test Selection	CLINITEK̀ 200+ Support
Autodetect	No, sent as URO-HEMACOMBI SG L
MULTISTIX	Yes
MULTISTIX 10 SG	Yes
MULTISTIX 9 SG	Yes
MULTISTIX 8 SG	Yes
MULTISTIX SG	Yes
MULTISTIX SG L	**NO**
N-MULTISTIX SG	Yes
NEPHROSTIX L	Yes
URO-HEMACOMBISTIX	Yes
URO-HEMACOMBISTIX SG L	Yes, sent as URO-HEMACOMBI SG L
URO-LABSTIX SG	**NO**
URO-LABSTIX SG L	Yes

For the test strips for which the CLINITEK® 200+ does not provide support, the ID message will be sent with the selected test name. It is the user's responsibility to ensure that the data collection system can accept the unsupported test strip name.

Data Set Information

- Each data set consists of 246 characters (248 characters if the Computer Checksum option is set to ON) if the 'Enter Sample ID' option is set to OFF and 312 characters (314 characters if the Computer Checksum option is set to ON) if the 'Enter Sample ID' option is set to ON. A data set contains the results for one test strip.

- An "STX" is output as the first character of each set.

- If the Computer Checksum option is set to ON, a checksum of all bytes sent between the STX and ETX is obtained and truncated to 8 bits. This is sent as two hexadecimal digits 0 thru F, the
- most significant four bits first. These two ASCII characters are sent preceding the ETX.

- An "ETX" is output as the last character of each set.

Data Set Output Format

Enter Sample ID set to OFF

```
stxcrlf                           (3 characters)
#A-AAA••••••BB-BB-BBcrlf (22 characters)    (25 characters total)
GLUI••HHHHHHHHHHHHHHHcrlf(22 characters)    (47 characters total)
BILI••HHHHHHHHHHHHHHHcrlf(22 characters)    (69 characters total)
CCCI••HHHHHHHHHHHHHHHcrlf(22 characters)    (91 characters total)
DDI•••HHHHHHHHHHHHHHHcrlf(22 characters)    (113 characters total)
EEEI••HHHHHHHHHHHHHHHcrlf(22 characters)    (135 characters total)
pHI•••HHHHHHHHHHHHHHHcrlf(22 characters)    (157 characters total)
PROI••HHHHHHHHHHHHHHHcrlf(22 characters)    (179 characters total)
FFFI••HHHHHHHHHHHHHHHcrlf(22 characters)    (201 characters total)
NITI••HHHHHHHHHHHHHHHcrlf(22 characters)    (223 characters total)
GGGI••HHHHHHHHHHHHHHHcrlf(22 characters)    (245 characters total)
etx                      (1 character)      (246 characters total)
OR
ck1ck2etx                (3 characters)     (248 characters total)
```

Enter Sample ID set to ON

```
stxcrlf                    (3 characters)
#A-AAA••••••BB-BB-BBcrlf (22 characters)    (25 characters total)
ID=JJJJJJJJJJJJJ•••crlf  (22 characters)    (47 characters total)
Color:•KKKKKKKKKK•••crlf (22 characters)    (69 characters total)
Clarity:•LLLLLLLLLL•crlf (22 characters)    (91 characters total)
GLUI••HHHHHHHHHHHHHHcrlf (22 characters)    (113 characters total)
BILI••HHHHHHHHHHHHHHcrlf (22 characters)    (135 characters total)
CCCI••HHHHHHHHHHHHHHcrlf (22 characters)    (157 characters total)
DD••••HHHHHHHHHHHHHHcrlf (22 characters)    (179 characters total)
EEEI••HHHHHHHHHHHHHHcrlf (22 characters)    (201 characters total)
pH••••HHHHHHHHHHHHHHcrlf (22 characters)    (223 characters total)
PROI••HHHHHHHHHHHHHHcrlf (22 characters)    (245 characters total)
FFFI••HHHHHHHHHHHHHHcrlf (22 characters)    (267 characters total)
NITI••HHHHHHHHHHHHHHcrlf (22 characters)    (289 characters total)
GGGI••HHHHHHHHHHHHHHcrlf (22 characters)    (311 characters total)
etx                        (1 character)    (312 characters total)
OR
ck1ck2etx                  (3 characters)   (314 characters total)
```

Variables:

•:	Represents a space.
stx:	START OF TEXT character (02H, 5).
ck1:	upper 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
ck2:	lower 4 bits of an 8 bit bytes checksum converted to an ASCII character "0-9 or A-F".
etx:	END OF TEXT character (03H,).
cr:	Represents the carriage return character (0DH, ^M).
lf:	Represents the line feed character (0AH, ^J).
A-AAA:	Represents the SEQ#.
BB-BB-BB:	Represents the date of the test. The date may be displayed in MM-DD-YY, DD-MM-YY, or YY-MM-DD format.
CCC:	Represents the language/units dependent test label for Ketone.
DD.:	Represents the language/units dependent test label for SG
EEE:	Represents the language/units dependent test label for Occult Blood.
FFF:	Represents the language/units dependent test label for Urobilinogen
GGG:	Represents the language/units dependent test label. for Leukocyte.
H:	Represents the test result label. This field is right justified. Each test result label contains 14 characters. Character positions not used are filled with spaces.
I:	Sent as an asterisk (*) if the result is positive; otherwise sent as a space.
J:	Represents the Sample ID. This field is left justified. The Sample ID may be a maximum of 13 alphanumeric characters. Endashes (-) are not supported by the CLINITEK® 200+. It is the responsibility of the user to ensure that the endash is not a part of the ID.
K:	Represents the Color value. This field is left justified and contains a maximum of ten characters.
L:	Represents the Clarity value. This field is left justified and contains a maximum of ten characters.

Example with Enter Sample ID set to OFF

```
#0-021      08-13-97
GLU         NEGATIVE
BIL         NEGATIVE
KET         NEGATIVE
SG             1.025
BLO*           TRACE
pH               6.5
PRO         NEGATIVE
URO      1.0 E.U./dL
NIT*        POSITIVE
LEU*           SMALL
```

Example with Sample ID set to ON:

```
#0-021      08-13-97
ID: ALP2345676543
Color: YELLOW
Clarity: CLEAR
GLU         NEGATIVE
BIL         NEGATIVE
KET         NEGATIVE
SG             1.025
BLO*           TRACE
pH               6.5
PRO         NEGATIVE
URO      1.0 E.U./dL
NIT*        POSITIVE
LEU*           SMALL
```

NOTES:

1. The SEQ # consists of the prefix number and index number. It is created from the CLINITEK 500 SEQ#. Starting from the left of the CLINITEK 500 SEQ#, position 1 is dropped, position 2 becomes the prefix digit, an endash is appended, and then positions 3 through 5 are used as the index portion of the SEQ#.

2. The order of transmission for test results is the order as defined onScreen: Tests Reported and Their Order. It is the responsibility of the user to define Color as the first test to be reported and Clarity as the second test to be reported.

3. The test abbreviation is a three character left justified field. For SG and pH, the third character is a space.

4. Positive urine chemistry test results are marked with an asterisk. The asterisk is located in the space directly to the right of the test abbreviation. Since the CLINITEK®200+ does not flag SG or pH results as positive, the test results for SG and pH are never marked as positive.

5. Color and Clarity results are never marked as positive.

6. Edited test results are never marked.

7. The test result field may be replaced by '..........ERROR' for all tests in a record. The word 'ERROR' is language selection specific.

8. The Sample ID field does not support the endash (-). It is the responsibility of the user to ensure that the endash is not a part of the ID.

9. The Tech ID data field is NOT transmitted.

10. Sample IDs must be set to ON in order for Color and/or Clarity to be reported.

APPENDIX D

Result Value Conversions From CLINITEK® 500 to CLINITEK® 200+

English Conventional

Supports CLINITEK® 200+ Program A4

	English Conventional with PLUS System set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVE 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIVE 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIVE SMALL MODERATE LARGE	no conversion required	NEGATIVE SMALL MODERATE LARGE
Ketone (KET)	NEGATIVE TRACE 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIVE TRACE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLO)	NEGATIVE TRACE-INTACT TRACE-LYSED SMALL MODERATE LARGE	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE TRACE TRACE SMALL MODERATE LARGE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVE TRACE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE

English Conventional with PLUS System set to OFF		
Test **CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU) NEGATIVE TRACE SMALL MODERATE LARGE	no conversion required	NEGATIVE TRACE SMALL MODERATE LARGE
Color (COL) LT. YELLOW YELLOW DK. YELLOW LT. ORANGE ORANGE DK. ORANGE LT. RED RED DK. RED LT. GREEN GREEN DK. GREEN LT. BLUE BLUE DK. BLUE LT. BROWN BROWN DK. BROWN	**COL >>>>>> Color** >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	 STRAW YELLOW DK YELLOW AMBER ORANGE ORANGE RED RED RED GREEN GREEN GREEN OTHER OTHER OTHER OTHER OTHER OTHER
Clarity (CLA) CLEAR SL CLOUDY CLOUDY TURBID OTHER	**CLA >>>>>> Clarity** no conversion required	 CLEAR SL CLOUDY CLOUDY TURBID OTHER
Invalid Result Value ERROR	no conversion required	ERROR

Supports CLINITEK® 200+ Program A4

	English Conventional with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin (BIL)	NEGATIVE 1+ 2+ 3+	no conversion required	NEGATIVE 1+ 2+ 3+
Ketone (KET)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLO)	NEGATIVE TRACE-INTACT TRACE-LYSED 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE TRACE TRACE 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE
Leukocytes (LEU)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+

English Conventional with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> Color**	
	LT. YELLOW	>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>	DK YELLOW
	LT. ORANGE	>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>	RED
	RED	>>>>>>>>>	RED
	DK. RED	>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>	GREEN
	LT. BROWN	>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>	OTHER
	LT. BLUE	>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Clarity**	
	CLEAR		CLEAR
	SL CLOUDY	no conversion required	SL CLOUDY
	CLOUDY		CLOUDY
	TURBID		TURBID
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

English Nordic

Supports CLINITEK® 200+ "For Finland" Option

English Nordic with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVE 1+ 2+ 3+ 4+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 2+ 2+ 3+
Bilirubin (BIL)	NEGATIVE 1+ 2+ 3+	no conversion required	NEGATIVE 1+ 2+ 3+
Ketone (KET)	NEGATIVE 1+ 2+ 3+ 4+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLD)	NEGATIVE +/- INTACT +/- 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 1+ 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE +/- 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE NEGATIVE 1+ 2+ 3+
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NORMAL NORMAL 1+ 2+ 3+
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE

Test	CLINITEK 500	English Nordic with PLUS System set to OFF >>>>>>>>>>>	CLINITEK 200+
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>>	NEGATIVE
	1+	>>>>>>>>>>	1+
	2+	>>>>>>>>>>	1+
	3+	>>>>>>>>>>	2+
	4+	>>>>>>>>>>	3+
Color (COL)		**COL >>>>>> Color**	
	LT. YELLOW	>>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>>	RED
	RED	>>>>>>>>>>	RED
	DK. RED	>>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>>	GREEN
	LT. BROWN	>>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>>	OTHER
	LT. BLUE	>>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Clarity**	
	CLEAR		CLEAR
	SL CLOUDY	no result conversion	SL CLOUDY
	CLOUDY	required	CLOUDY
	TURBID		TURBID
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

Supports CLINITEK® 200+ "For Finland" Option

| | English Nordic with PLUS System set to ON | | |
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Glucose (GLU)	NEGATIVE TRACE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 2+ 2+ 3+
Bilirubin (BIL)	NEGATIVE 1+ 2+ 3+	no conversion required	NEGATIVE 1+ 2+ 3+
Ketone (KET)	NEGATIVE TRACE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLD)	NEGATIVE +/- INTACT +/- 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 1+ 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE NEGATIVE 1+ 2+ 3+
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NORMAL NORMAL 1+ 2+ 3+
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE
Leukocytes (LEU)	NEGATIVE TRACE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVE 1+ 1+ 2+ 3+

Test	CLINITEK 500	English Nordic with PLUS System set to ON >>>>>>>>>>	CLINITEK 200+
Color (COL)		**COL >>>>>> Color**	
	LT. YELLOW	>>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>>	RED
	RED	>>>>>>>>>>	RED
	DK. RED	>>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>>	GREEN
	LT. BROWN	>>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>>	OTHER
	LT. BLUE	>>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Clarity**	
	CLEAR		CLEAR
	SL CLOUDY	no conversion required	SL CLOUDY
	CLOUDY		CLOUDY
	TURBID		TURBID
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

English S.I.

Supports CLINITEK® 200+ Program C4

English S.I. with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVE 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L	no conversion required	NEGATIVE 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L
Bilirubin (BIL)	NEGATIVE SMALL MODERATE LARGE	no conversion required	NEGATIVE SMALL MODERATE LARGE
Ketone (KET)	NEGATIVE TRACE 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	no conversion required	NEGATIVE TRACE 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLD)	NEGATIVE TRACE-INTACT TRACE-LYSED Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVE TRACE TRACE SMALL MODERATE LARGE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 0.3 g/L 1.0 g/L >=3.0 g/L	no conversion required	NEGATIVE TRACE 0.3 g/L 1.0 g/L >=3.0 g/L
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE

English S.I. with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU)	NEGATIVE	>>>>>>>>>	NEGATIVE
	Ca 15 Leu/uL	>>>>>>>>>	Ca 15 Cells/uL
	Ca 70 Leu/uL	>>>>>>>>>	Ca 70 Cells/uL
	Ca 125 Leu/uL	>>>>>>>>>	Ca125 Cells/uL
	Ca 500 Leu/uL	>>>>>>>>>	Ca500 Cells/uL
Color (COL)		**COL >>>>>> Color**	
	LT. YELLOW	>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>	RED
	RED	>>>>>>>>>	RED
	DK. RED	>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>	GREEN
	LT. BROWN	>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>	OTHER
	LT. BLUE	>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Clarity**	
	CLEAR		CLEAR
	SL CLOUDY	no conversion required	SL CLOUDY
	CLOUDY		CLOUDY
	TURBID		TURBID
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

Supports CLINITEK® 200+ Program C4

	English S.I. with PLUS System set to ON		
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Glucose (GLU)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Bilirubin (BIL)	NEGATIVE 1+ 2+ 3+	no conversion required	NEGATIVE 1+ 2+ 3+
Ketone (KET)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (BLD)	NEGATIVE TRACE-INTACT TRACE-LYSED 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVE TRACE TRACE 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+
Urobilinogen (UBG)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIVE POSITIVE	no conversion required	NEGATIVE POSITIVE
Leukocytes (LEU)	NEGATIVE TRACE 1+ 2+ 3+	no conversion required	NEGATIVE TRACE 1+ 2+ 3+

English S.I. with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> Color**	
	LT. YELLOW	>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>	RED
	RED	>>>>>>>>>	RED
	DK. RED	>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>	GREEN
	LT. BROWN	>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>	OTHER
	LT. BLUE	>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Clarity**	
	CLEAR		CLEAR
	SL CLOUDY	no conversion required	SL CLOUDY
	CLOUDY		CLOUDY
	TURBID		TURBID
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

French Conventional

Supports CLINITEK® 200+ Program G4

French Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIF TRACES 2.5 g/L 5.0 g/L >=10.0 g/L	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF 1.0 g/L 2.5 g/L 5.0 g/L >=10.0 g/L
Bilirubin (BIL)	NEGATIF FAIBLE MOYEN FORT	no conversion required	NEGATIF FAIBLE MOYEN FORT
Ketone (CET)	NEGATIF TRACES 0.15 g/L 0.4 g/L >=0.8 g/L	no conversion required	NEGATIF TRACES 0.15 g/L 0.4 g/L >=0.8 g/L
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSE env. 25 GR/uL env. 80 GR/uL env. 200 GR/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF env. 10 GR/uL env. 10 GR/uL env. 25 GR/uL env. 80 GR/uL env. 200 GR/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L	no conversion required	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L
Urobilinogen (URO)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL	no conversion required	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF

French Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU)	NEGATIF env. 15 GB/uL env. 70 GB/uL env. 125 GB/uL env. 500 GB/uL	no conversion required	NEGATIF env. 15 GB/uL env. 70 GB/uL env. 125 GB/uL env. 500 GB/uL
Color (COL)		**COL >>>>>> COULEUR**	
	JAUNE CLR.	>>>>>>>>>	PAILLE
	JAUNE	>>>>>>>>>	JAUNE
	JAUNE FONC.	>>>>>>>>>	JAUN FONCE
	ORANGE CLR.	>>>>>>>>>	AMBRE
	ORANGE	>>>>>>>>>	ORANGE
	ORANGE FONC.	>>>>>>>>>	ORANGE
	ROUGE CLR.	>>>>>>>>>	ROUGE
	ROUGE	>>>>>>>>>	ROUGE
	ROUGE FONC.	>>>>>>>>>	ROUGE
	VERT CLR.	>>>>>>>>>	VERT
	VERT	>>>>>>>>>	VERT
	VERT FONC.	>>>>>>>>>	VERT
	BLEU CLR.	>>>>>>>>>	AUTRE
	BLEU	>>>>>>>>>	AUTRE
	BLEU FONC.	>>>>>>>>>	AUTRE
	MARRON CLR.	>>>>>>>>>	AUTRE
	MARRON	>>>>>>>>>	AUTRE
	MARRON FONC.	>>>>>>>>>	AUTRE
Clarity (ASP)		**ASP >>>>>> ASPECT**	
	LIMPIDE		LIMPIDE
	LEG TROUB	no conversion required	LEG TROUB
	TROUBLE		TROUBLE
	OPAQUE		OPAQUE
	AUTRE		AUTRE
Invalid Result Value	ERREUR	no conversion required	ERREUR

Supports CLINITEK® 200+ Program G40100

	French Conventional with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIF TRACES 1+ 2+ 3+	no conversion required	NEGATIF TRACES 1+ 2+ 3+
Bilirubin (BIL)	NEGATIF 1+ 2+ 3+	no conversion required	NEGATIF 1+ 2+ 3+
Ketone (CET)	NEGATIF TRACES 1+ 2+ 3+	no conversion required	NEGATIF TRACES 1+ 2+ 3+
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACES TRACES 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 1+ 2+ 3+	no conversion required	NEGATIF TRACES 1+ 2+ 3+
Urobilinogen (URO)	0.2 mg/Dl 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	no conversion required	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF
Leukocytes (LEU)	NEGATIF TRACES 1+ 2+ 3+	no conversion required	NEGATIF TRACES 1+ 2+ 3+

French Conventional with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> COULEUR**	
	CLR. JAUNE	>>>>>>>>>>	PAILLE
	JAUNE	>>>>>>>>>>	JAUNE
	FONC. JAUNE	>>>>>>>>>>	JAUN FONCE
	CLR. ORANGE	>>>>>>>>>>	AMBRE
	ORANGE	>>>>>>>>>>	ORANGE
	FONC. ORANGE	>>>>>>>>>>	ORANGE
	CLR. ROUGE	>>>>>>>>>>	ROUGE
	ROUGE	>>>>>>>>>>	ROUGE
	FONC. ROUGE	>>>>>>>>>>	ROUGE
	CLR. VERT	>>>>>>>>>>	VERT
	VERT	>>>>>>>>>>	VERT
	FONC. VERT	>>>>>>>>>>	VERT
	CLR. BLEU	>>>>>>>>>>	AUTRE
	BLEU	>>>>>>>>>>	AUTRE
	FONC. BLEU	>>>>>>>>>>	AUTRE
	CLR. MARRON	>>>>>>>>>>	AUTRE
	MARRON	>>>>>>>>>>	AUTRE
	FONC. MARRON	>>>>>>>>>>	AUTRE
Clarity (ASP)		**ASP >>>>>> ASPECT**	
	LIMPIDE		LIMPIDE
	LEG TROUB	no conversion required	LEG TROUB
	TROUBLE		TROUBLE
	OPAQUE		OPAQUE
	AUTRE		AUTRE
Invalid Result Value	ERREUR	no conversion required	ERREUR

French S.I.

Support for CLINITEK® 200+ Program H4

French S.I. with PLUS system set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>** **CLINITEK 200+**
Glucose (GLU)	NEGATIF 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L	no conversion required NEGATIF 5.5 mmol/L 14 mmol/L 28 mmol/L >=55 mmol/L
Bilirubin (BIL)	NEGATIF FAIBLE MOYEN FORT	no conversion required NEGATIF FAIBLE MOYEN FORT
Ketone (CET)	NEGATIF TRACES 1.5 mmol/L 3.9 mmol/L >=7.8 mmol/L	>>>>>>>>>> NEGATIF >>>>>>>>>> TRACE >>>>>>>>>> 1.5 mmol/L >>>>>>>>>> 3.9 mmol/L >>>>>>>>>> >=7.8 mmol/L
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required <= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSED FAIBLE MOYEN FORT	>>>>>>>>>> NEGATIF >>>>>>>>>> TRACE >>>>>>>>>> TRACE >>>>>>>>>> FAIBLE >>>>>>>>>> MOYEN >>>>>>>>>> FORT
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 0.3 g/L 1.0 g/L >=3.0 g/L	>>>>>>>>>> NEGATIF >>>>>>>>>> TRACE >>>>>>>>>> 0.3 g/L >>>>>>>>>> 1.0 g/L >>>>>>>>>> >=3.0 g/L
Urobilinogen (URO)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required 3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIF POSITIF	no conversion required NEGATIF POSITIF

French S.I. with PLUS system set to OFF			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Leukocytes (LEU)	NEGATIF	>>>>>>>>>	NEGATIF
	TRACES	>>>>>>>>>	TRACE
	FAIBLE	>>>>>>>>>	FAIBLE
	MOYEN	>>>>>>>>>	MOYEN
	FORT	>>>>>>>>>	FORT
Color (COL)		**COL >>>>>> COULEUR**	
	CLR. JAUNE	>>>>>>>>>	PAILLE
	JAUNE	>>>>>>>>>	JAUNE
	FONC. JAUNE	>>>>>>>>>	JAUN FONCE
	CLR. ORANGE	>>>>>>>>>	AMBRE
	ORANGE	>>>>>>>>>	ORANGE
	FONC. ORANGE	>>>>>>>>>	ORANGE
	CLR. ROUGE	>>>>>>>>>	ROUGE
	ROUGE	>>>>>>>>>	ROUGE
	FONC. ROUGE	>>>>>>>>>	ROUGE
	CLR. VERT	>>>>>>>>>	VERT
	VERT	>>>>>>>>>	VERT
	FONC. VERT	>>>>>>>>>	VERT
	CLR. BLEU	>>>>>>>>>	AUTRE
	BLEU	>>>>>>>>>	AUTRE
	FONC. BLEU	>>>>>>>>>	AUTRE
	CLR. MARRON	>>>>>>>>>	AUTRE
	MARRON	>>>>>>>>>	AUTRE
	FONC. MARRON	>>>>>>>>>	AUTRE
Clarity (ASP)		**ASP>>>>>> ASPECT**	
	LIMPIDE		LIMPIDE
	LEG TROUB	no conversion required	LEG TROUB
	TROUBLE		TROUBLE
	OPAQUE		OPAQUE
	AUTRE		AUTRE
Invalid Result Value	ERREUR	no conversion required	ERREUR

Support for CLINITEK® 200+ Program H4

	French S.I. with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACE 1+ 2+ 3+
Bilirubin (BIL)	NEGATIF 1+ 2+ 3+	no conversion required	NEGATIF 1+ 2+ 3+
Ketone (CET)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACE 1+ 2+ 3+
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SNG)	NEGATIF TRACES-INTACT TRACES-LYSED 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACE TRACE 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACE 1+ 2+ 3+
Urobilinogen (URO)	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L	no conversion required	3.2 umol/L 16 umol/L 33 umol/L 66 umol/L >=131 umol/L
Nitrite (NIT)	NEGATIF POSITIF	no conversion required	NEGATIF POSITIF
Leukocytes (LEU)	NEGATIF TRACES 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIF TRACE 1+ 2+ 3+

French S.I. with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> COULEUR**	
	CLR. JAUNE	>>>>>>>>>>	PAILLE
	JAUNE	>>>>>>>>>>	JAUNE
	FONC. JAUNE	>>>>>>>>>>	JAUN FONCE
	CLR. ORANGE	>>>>>>>>>>	AMBRE
	ORANGE	>>>>>>>>>>	ORANGE
	FONC. ORANGE	>>>>>>>>>>	ORANGE
	CLR. ROUGE	>>>>>>>>>>	ROUGE
	ROUGE	>>>>>>>>>>	ROUGE
	FONC. ROUGE	>>>>>>>>>>	ROUGE
	CLR. VERT	>>>>>>>>>>	VERT
	VERT	>>>>>>>>>>	VERT
	FONC. VERT	>>>>>>>>>>	VERT
	CLR. BLEU	>>>>>>>>>>	AUTRE
	BLEU	>>>>>>>>>>	AUTRE
	FONC. BLEU	>>>>>>>>>>	AUTRE
	CLR. MARRON	>>>>>>>>>>	AUTRE
	MARRON	>>>>>>>>>>	AUTRE
	FONC. MARRON	>>>>>>>>>>	AUTRE
Clarity (CLA)		**CLA >>>>>> ASPECT**	
	LIMPIDE		LIMPIDE
	LEG TROUB	no result conversion	LEG TROUB
	TROUBLE	required	TROUBLE
	OPAQUE		OPAQUE
	AUTRE		AUTRE
Invalid Result Value	ERRUER	no conversion required	ERRUER

German Conventional

Supports CLINITEK® 200+ Program F4

German Conventional with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIV 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIV 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIV SCHWACH MAESSIG STARK	no conversion required	NEGATIV SCHWACH MAESSIG STARK
Ketone (KET)	NEGATIV SPUR 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIV SPUR 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OBL)	0 Ery/uL Ca 10 Ery/uL Ca 10 Ery/uL Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL	no conversion required	0 Ery/uL Ca 10 Ery/uL Ca 10 Ery/uL Ca 25 Ery/uL Ca 80 Ery/uL Ca 200 Ery/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIV SPUR 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion needed	NEGATIV SPUR 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (UBG)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	no conversion needed	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIV POSITIV	no conversion needed >>>>>>>>>	NEGATIV POSITIV

	German Conventional with PLUS System set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU)	0 Leu/uL		0 Leu/uL
	Ca 15 Leu/uL		Ca 15 Leu/uL
	Ca 70 Leu/uL	no conversion required	Ca 70 Leu/uL
	Ca 125 Leu/uL		Ca 125 Leu/uL
	Ca 500 Leu/uL		Ca 500 Leu/uL
Color (COL)		**COL >>>>>> Farbe**	
	HELL GELB	>>>>>>>>>	HELL
	GELB	>>>>>>>>>	GELB
	DUNK. GELB	>>>>>>>>>	DUNKEL
	HELL ORANGE	>>>>>>>>>	BRAEUNL.
	ORANGE	>>>>>>>>>	ORANGE
	DUNK. ORANGE	>>>>>>>>>	ORANGE
	HELL ROT	>>>>>>>>>	ROT
	ROT	>>>>>>>>>	ROT
	DUNK. ROT	>>>>>>>>>	ROT
	HELL GRUEN	>>>>>>>>>	GRUEN
	GRUEN	>>>>>>>>>	GRUEN
	DUNK. GRUEN	>>>>>>>>>	GRUEN
	HELL BRAUN	>>>>>>>>>	ANDERS
	BRAUN	>>>>>>>>>	ANDERS
	DUNK. BRAUN	>>>>>>>>>	ANDERS
	HELL BLAU	>>>>>>>>>	ANDERS
	BLAU	>>>>>>>>>	ANDERS
	DUNK. BLAU	>>>>>>>>>	ANDERS
Clarity (ASP)		**ASP >>>>>> Klarheit**	
	KLAR		KLAR
	FLOCKIG	no conversion required	FLOCKIG
	S. FLOCKIG		S. FLOCKIG
	TRUEB		TRUEB
	ANDERS		ANDERS
Invalid Result Value	FEHLER	no conversion required	FEHLER

Supports CLINITEK® 200+ Program F4

	German Conventional with PLUS System set to ON		
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Glucose (GLU)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIV SPUR 1+ 2+ 3+
Bilirubin (BIL)	NEGATIV 1+ 2+ 3+	no conversion required	NEGATIV 1+ 2+ 3+
Ketone (KET)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIV SPUR 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OBL)	NEGATIV SPUR-ZELLEN SPUR-LYSE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIV SPUR SPUR 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIV SPUR 1+ 2+ 3+
Urobilinogen (UBG)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL	no conversion required	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0mg/dL
Nitrite (NIT)	NEGATIV POSITIV	no conversion required	NEGATIV POSITIV
Leukocytes (LEU)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIVE SPUR 1+ 2+ 3+

German Conventional with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> Farbe**	
	HELL GELB	>>>>>>>>>	HELL
	GELB	>>>>>>>>>	GELB
	DUNK. GELB	>>>>>>>>>	DUNKEL
	HELL ORANGE	>>>>>>>>>	BRAEUNL.
	ORANGE	>>>>>>>>>	ORANGE
	DUNK. ORANGE	>>>>>>>>>	ORANGE
	HELL ROT	>>>>>>>>>	ROT
	ROT	>>>>>>>>>	ROT
	DUNK. ROT	>>>>>>>>>	ROT
	HELL GRUEN	>>>>>>>>>	GRUEN
	GRUEN	>>>>>>>>>	GRUEN
	DUNK. GRUEN	>>>>>>>>>	GRUEN
	HELL BRAUN	>>>>>>>>>	ANDERS
	BRAUN	>>>>>>>>>	ANDERS
	DUNK. BRAUN	>>>>>>>>>	ANDERS
	HELL BLAU	>>>>>>>>>	ANDERS
	BLAU	>>>>>>>>>	ANDERS
	DUNK. BLAU	>>>>>>>>>	ANDERS
Clarity (ASP)		**ASP >>>>>> Klarheit**	
	KLAR		KLAR
	FLOCKIG	no conversion required	FLOCKIG
	S. FLOCKIG		S. FLOCKIG
	TRUEB		TRUEB
	ANDERS		ANDERS
Invalid Result Value	FEHLER	no conversion required	FEHLER

German S.I.

Supports CLINITEK® 200+ Program F4

German S.I. with PLUS System set to OFF		
Test	**CLINITEK 500** >>>>>>>>>>	**CLINITEK 200+**
Glucose (GLU)	NEGATIV >>>>>>>>>>	NEGATIV
	5.5 mmol/L >>>>>>>>>>	100 mg/dL
	14 mmol/L >>>>>>>>>>	250 mg/dL
	28 mmol/L >>>>>>>>>>	500 mg/dL
	>=55 mmol/L >>>>>>>>>>	>=1000 mg/dL
Bilirubin (BIL)	NEGATIV	NEGATIV
	SCHWACH	SCHWACH
	MAESSIG no conversion required	MAESSIG
	STARK	STARK
Ketone (KET)	NEGATIV >>>>>>>>>>	NEGATIV
	SPUR >>>>>>>>>>	SPUR
	1.5 mmol/L >>>>>>>>>>	15 mg/dL
	3.9 mmol/L >>>>>>>>>>	40 mg/dL
	>= 7.8 mmol/L >>>>>>>>>>	>=80 mg/dL
Specific Gravity (SG)	<= 1.005	<= 1.005
	1.010	1.010
	1.015	1.015
	1.020 no conversion required	1.020
	1.025	1.025
	>=1.030	>=1.030
Blood (OBL)	0 Ery/uL >>>>>>>>>>	0 Ery/uL
	Ca 10 Ery/uL >>>>>>>>>>	Ca 10 Ery/uL
	Ca 10 Ery/uL >>>>>>>>>>	Ca 10 Ery/uL
	Ca 25 Ery/uL >>>>>>>>>>	Ca 25 Ery/uL
	Ca 80 Ery/uL >>>>>>>>>>	Ca 80 Ery/uL
	Ca 200 Ery/uL >>>>>>>>>>	Ca 200 Ery/uL
pH (pH)	5.0	5.0
	5.5	5.5
	6.0	6.0
	6.5	6.5
	7.0 no conversion required	7.0
	7.5	7.5
	8.0	8.0
	8.5	8.5
	>=9.0	>=9.0
Protein (PRO)	NEGATIV >>>>>>>>>>	NEGATIV
	SPUR >>>>>>>>>>	SPUR
	0.3 g/L >>>>>>>>>>	30 mg/dL
	1.0 g/L >>>>>>>>>>	100 mg/dL
	>= 3.0 g/L >>>>>>>>>>	>=300 mg/dL
Urobilinogen (UBG)	3.2 umol/L >>>>>>>>>>	0.2 mg/dL
	16 umol/L >>>>>>>>>>	1.0 mg/dL
	33 umol/L >>>>>>>>>>	2.0 mg/dL
	66 umol/L >>>>>>>>>>	4.0 mg/dL
	>= 131 umol/L >>>>>>>>>>	>=8.0 mg/dL
Nitrite (NIT)	NEGATIV no conversion needed	NEGATIV
	POSITIV >>>>>>>>>>	POSITIV

Test	CLINITEK 500	German S.I. with PLUS System set to OFF >>>>>>>>>>	CLINITEK 200+
Leukocytes (LEU)	0 Leu/uL Ca 15 Leu/uL Ca 70 Leu/uL Ca 125 Leu/uL Ca 500 Leu/uL	no conversion required	0 Leu/uL Ca 15 Leu/uL Ca 70 Leu/uL Ca 125 Leu/uL Ca 500 Leu/uL
Color (COL)	HELL GELB GELB DUNK. GELB HELL ORANGE ORANGE DUNK. ORANGE HELL ROT ROT DUNK. ROT HELL GRUEN GRUEN DUNK. GRUEN HELL BRAUN BRAUN DUNK. BRAUN HELL BLAU BLAU DUNK. BLAU	**COL >>>>>> Farbe** >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	HELL GELB DUNKEL BRAEUNL. ORANGE ORANGE ROT ROT ROT GRUEN GRUEN GRUEN ANDERS ANDERS ANDERS ANDERS ANDERS ANDERS
Clarity (CLA)	KLAR FLOCKIG S. FLOCKIG TRUEB ANDERS	**CLA >>>>>> Klarheit** no conversion required	KLAR FLOCKIG S. FLOCKIG TRUEB ANDERS
Invalid Result Value	FEHLER	no conversion required	FEHLER

APPENDIX D

Supports CLINITEK® 200+ Program F4

	German S.I. with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIV SPUR 1+ 2+ 3+
Bilirubin (BIL)	NEGATIV 1+ 2+ 3+	no conversion required	NEGATIV 1+ 2+ 3+
Ketone (KET)	NEGATIV SPUR 1+ 2+ 3+	no conversion required	NEGATIV SPUR 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OBL)	NEGATIV SPUR-ZELLEN SPUR-LYSE 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIV SPUR SPUR 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIV SPUR 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIV SPUR 1+ 2+ 3+
Urobilinogen (UBG)	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	0.2 mg/dL 1.0 mg/dL 2.0 mg/dL 4.0 mg/dL >=8.0 mg/dL
Nitrite (NIT)	NEGATIV POSITIV	>>>>>>>>> >>>>>>>>>	NEGATIV POSITIV
Leukocytes (LEU)	NEGATIV SPUR 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVE SPUR 1+ 2+ 3+

German S.I. with PLUS System set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> Farbe**	
	HELL GELB	>>>>>>>>>	HELL
	GELB	>>>>>>>>>	GELB
	DUNK. GELB	>>>>>>>>>	DUNKEL
	HELL ORANGE	>>>>>>>>>	BRAEUNL.
	ORANGE	>>>>>>>>>	ORANGE
	DUNK. ORANGE	>>>>>>>>>	ORANGE
	HELL ROT	>>>>>>>>>	ROT
	ROT	>>>>>>>>>	ROT
	DUNK. ROT	>>>>>>>>>	ROT
	HELL GRUEN	>>>>>>>>>	GRUEN
	GRUEN	>>>>>>>>>	GRUEN
	DUNK. GRUEN	>>>>>>>>>	GRUEN
	HELL BRAUN	>>>>>>>>>	ANDERS
	BRAUN	>>>>>>>>>	ANDERS
	DUNK. BRAUN	>>>>>>>>>	ANDERS
	HELL BLAU	>>>>>>>>>	ANDERS
	BLAU	>>>>>>>>>	ANDERS
	DUNK. BLAU	>>>>>>>>>	ANDERS
Clarity (ASP)		**ASP>>>>>> Klarheit**	
	KLAR		KLAR
	FLOCKIG	no conversion required	FLOCKIG
	S. FLOCKIG		S. FLOCKIG
	TRUEB		TRUEB
	ANDERS		ANDERS
Invalid Result Value	FEHLER	no conversion required	FEHLER

Italian

Supports CLINITEK® 200+ Program E4

Italian with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVO 1.0 g/L 2.5 g/L 5.0 g/L >=10.0 g/L	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO 0.1 g/dL 0.25 g/dL 0.5 g/dL >=1.0 g/dL
Bilirubin (BIL)	NEGATIVO LEGGERO MEDIO FORTE	no conversion required	NEGATIVO LEGGERO MEDIO FORTE
Ketone (KET)	NEGATIVO TRACCE 15 mg/dL 40 mg/dL >=80 mg/dL	no conversion required	NEGATIVO TRACCE 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (PS)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO TRACCE(INT.) TRACCE(LIS.) LEGGERO MEDIO FORTE	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO TRACCE TRACCE LEGGERO MEDIO FORTE
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO TRACCE 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVO TRACCE 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO

Italian with PLUS System set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU)	NEGATIVO	>>>>>>>>>>	NEGATIVO
	Ca 15 Cel/uL	>>>>>>>>>>	Ca 15 Cells/uL
	Ca 70 Cel/uL	>>>>>>>>>>	Ca 70 Cells/uL
	Ca 125 Cel/uL	>>>>>>>>>>	Ca125 Cells/uL
	Ca 500 Cel/uL	>>>>>>>>>>	Ca500 Cells/uL
Color (COL)		**COL >>>>>> Colore**	
	CHIA. GIALLO	>>>>>>>>>>	PAGLIER.
	GIALLO	>>>>>>>>>>	GIALLO
	SCUR. GIALLO	>>>>>>>>>>	GIALLO SC.
	CHIA. ARANCIONE	>>>>>>>>>>	AMBRA
	ARANCIONE	>>>>>>>>>>	ARANCIO
	SCUR. ARANCIONE	>>>>>>>>>>	ARANCIO
	CHIA. ROSSO	>>>>>>>>>>	ROSSO
	ROSSO	>>>>>>>>>>	ROSSO
	SCUR. ROSSO	>>>>>>>>>>	ROSSO
	CHIA. VERDE	>>>>>>>>>>	VERDE
	VERDE	>>>>>>>>>>	VERDE
	SCUR. VERDE	>>>>>>>>>>	VERDE
	CHIA. AZZURO	>>>>>>>>>>	ALTRO
	AZZURO	>>>>>>>>>>	ALTRO
	SCUR. AZZURO	>>>>>>>>>>	ALTRO
	CHIA. MARRONE	>>>>>>>>>>	ALTRO
	MARRONE	>>>>>>>>>>	ALTRO
	SCUR. MARONE	>>>>>>>>>>	ALTRO
Clarity (ASP)		**ASP >>>>>> Aspetto**	
	LIMPIDA		LIMPIDA
	LEG. TORB	no conversion required	LEG. TORB
	TORBIDA		TORBIDA
	MOL.TORB		MOL.TORB
	ALTRO		ALTRO
Invalid Result Value	ERRORE	no conversion required	ERRORE

Supports CLINITEK® 200+ Program E40100

	Italian with PLUS System set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVO TRACCE 1+ 2+ 3+	no conversion required	NEGATIVO TRACCE 1+ 2+ 3+
Bilirubin (BIL)	NEGATIVO 1+ 2+ 3+	no conversion required	NEGATIVO 1+ 2+ 3+
Ketone (KET)	NEGATIVO TRACCE 1+ 2+ 3+	no conversion required	NEGATIVO TRACCE 1+ 2+ 3+
Specific Gravity (PS)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO TRACCE(INT.) TRACCE(LIS.) 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO TRACCE TRACCE 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO TRACCE 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	NEGATIVO TRACCE 1+ 2+ 3+
Urobilinogen (URO)	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO
Leukocytes (LEU)	NEGATIVO TRACCE 1+ 2+ 3+	no conversion required	NEGATIVO TRACCE 1+ 2+ 3+

Italian with PLUS System set to ON			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Color (COL)		**COL >>>>>> Colore**	
	CHIA. GIALLO	>>>>>>>>>	PAGLIER.
	GIALLO	>>>>>>>>>	GIALLO
	SCUR. GIALLO	>>>>>>>>>	GIALLO SC.
	CHIA. ARANCIONE	>>>>>>>>>	AMBRA
	ARANCIONE	>>>>>>>>>	ARANCIO
	SCUR. ARANCIONE	>>>>>>>>>	ARANCIO
	CHIA. ROSSO	>>>>>>>>>	ROSSO
	ROSSO	>>>>>>>>>	ROSSO
	SCUR. ROSSO	>>>>>>>>>	ROSSO
	CHIA. VERDE	>>>>>>>>>	VERDE
	VERDE	>>>>>>>>>	VERDE
	SCUR. VERDE	>>>>>>>>>	VERDE
	CHIA. AZZURO	>>>>>>>>>	ALTRO
	AZZURO	>>>>>>>>>	ALTRO
	SCUR. AZZURO	>>>>>>>>>	ALTRO
	CHIA. MARRONE	>>>>>>>>>	ALTRO
	MARRONE	>>>>>>>>>	ALTRO
	SCUR. MARONE	>>>>>>>>>	ALTRO
Clarity (ASP)		**ASP >>>>>> Aspetto**	
	LIMPIDA		LIMPIDA
	LEG. TORB	no conversion required	LEG. TORB
	TORBIDA		TORBIDA
	MOL.TORB		MOL.TORB
	ALTRO		ALTRO
Invalid Result Value	ERRORE	no conversion required	ERRORE

Kanji

Supports CLINITEK® 200+ Program B4

Kanji with PLUS system set to OFF		
Test	**CLINITEK 500**	**>>>>>>>>>>** **CLINITEK 200+**
Glucose (GLU)	- 0.1 g/L 0.25 g/L 0.5 g/L >=1.0 g/L	no conversion required - 0.1 g/dL 0.25 g/dL 0.5 g/dL >=1.0 g/dL
Bilirubin (BIL)	- 1+ 2+ 3+	no conversion required - 1+ 2+ 3+
Ketone (KET)	- +/- 1+ 2+ 3+	no conversion required - +/- 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required <= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OB)	- +/-INTACT +/-LYSED 1+ 2+ 3+	>>>>>>>>> - >>>>>>>>> +/- >>>>>>>>> +/- >>>>>>>>> 1+ >>>>>>>>> 2+ >>>>>>>>> 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	- +/- 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required - +/- 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required 0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	- +	no conversion required - +

Kanji with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (WBC)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Color (COL)		**COL >>>>>> Colore**	
	LT. YELLOW	>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>	RED
	RED	>>>>>>>>>	RED
	DK. RED	>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>	GREEN
	LT. BLUE	>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>	OTHER
	LT. BROWN	>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Aspetto**	
	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Invalid Result Value	ERROR	no conversion required	ERROR

APPENDIX D

	Kanji with PLUS system set to ON		
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Glucose (GLU)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Bilirubin (BIL)	- 1+ 2+ 3+	no conversion required	- 1+ 2+ 3+
Ketone (KET)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Specific Gravity (SG)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (OB)	- +/-INTACT +/-LYSED 1+ 2+ 3+	>>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>> >>>>>>>>>>	- +/- +/- 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+
Urobilinogen (URO)	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	no conversion required	0.1 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	- +	no conversion required	- +
Leukocytes (WBC)	- +/- 1+ 2+ 3+	no conversion required	- +/- 1+ 2+ 3+

Kanji with PLUS system set to ON			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Color (COL)		**COL >>>>>> Colore**	
	LT. YELLOW	>>>>>>>>>	STRAW
	YELLOW	>>>>>>>>>	YELLOW
	DK. YELLOW	>>>>>>>>>	DK. YELLOW
	LT. ORANGE	>>>>>>>>>	AMBER
	ORANGE	>>>>>>>>>	ORANGE
	DK. ORANGE	>>>>>>>>>	ORANGE
	LT. RED	>>>>>>>>>	RED
	RED	>>>>>>>>>	RED
	DK. RED	>>>>>>>>>	RED
	LT. GREEN	>>>>>>>>>	GREEN
	GREEN	>>>>>>>>>	GREEN
	DK. GREEN	>>>>>>>>>	GREEN
	LT. BLUE	>>>>>>>>>	OTHER
	BLUE	>>>>>>>>>	OTHER
	DK. BLUE	>>>>>>>>>	OTHER
	LT. BROWN	>>>>>>>>>	OTHER
	BROWN	>>>>>>>>>	OTHER
	DK. BROWN	>>>>>>>>>	OTHER
Clarity (CLA)		**CLA >>>>>> Aspetto**	
	-		-
	+/-	no conversion required	+/-
	1+		1+
	2+		2+
	OTHER		OTHER
Invalid Result Value	ERROR	no conversion required	ERROR

Spanish

Supports CLINITEK® 200+ Program D4

	Spanish with PLUS system set to OFF		
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Glucose (GLU)	NEGATIVO 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	no conversion required	NEGATIVO 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL
Bilirubin (BIL)	NEGATIVO BAJO MODERADO ALTO	no conversion required	NEGATIVO BAJO MODERADO ALTO
Ketone (CET)	NEGATIVO INDICIOS 15 mg/dL 40 mg/dL >=80 mg/dL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO 15 mg/dL 40 mg/dL >=80 mg/dL
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO IND.INTACTOS IND.HEMOLIZ. Apr 25 Hem/uL Apr 80 Hem/uL Apr 200 Hem/uL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO Apr 10 eri/uL Apr 10 eri/uL Apr 25 eri/uL Apr 80 eri/uL Apr 200 eri/uL
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO INDICIOS 30 mg/dL 100 mg/dL >=300 mg/dL	no conversion required	NEGATIVO INDICIO 30 mg/dL 100 mg/dL >=300 mg/dL
Urobilinogen (URO)	0.2 U.E./dL 1.0 U.E./dL 2.0 U.E./dL 4.0 U.E./dL >=8.0 U.E./dL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO

Spanish with PLUS system set to OFF			
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Leukocytes (LEU)	NEGATIVO	>>>>>>>>>	NEGATIVO
	Apr 15 Leu/uL	>>>>>>>>>	Apr 15 cel/uL
	Apr 70 Leu/uL	>>>>>>>>>	Apr 70 cel/uL
	Apr 125 Leu/uL	>>>>>>>>>	Apr 125 cel/uL
	Apr 500 Leu/uL	>>>>>>>>>	Apr 500 cel/uL
Color (COL)		**COL >>>>>> Color**	
	CL. AMARILLO	>>>>>>>>>	COLURICA
	AMARILLO	>>>>>>>>>	AMARILLO
	OSC. AMARILLO	>>>>>>>>>	AM. OSCURO
	CL. NARANJA	>>>>>>>>>	AMBAR
	NARANJA	>>>>>>>>>	ANARANJ
	OSC. NARANJA	>>>>>>>>>	ANARANJ
	CL. ROJO	>>>>>>>>>	ROJIZO
	ROJO	>>>>>>>>>	ROJIZO
	OSC. ROJO	>>>>>>>>>	ROJIZO
	CL. VERDE	>>>>>>>>>	VERDOSO
	VERDE	>>>>>>>>>	VERDOSO
	OSC. VERDE	>>>>>>>>>	VERDOSO
	CL. AZUL	>>>>>>>>>	OTROS
	AZUL	>>>>>>>>>	OTROS
	OSC. AZUL	>>>>>>>>>	OTROS
	CL. MARRON	>>>>>>>>>	OTROS
	MARRON	>>>>>>>>>	OTROS
	OSC. MARRON	>>>>>>>>>	OTROS
Clarity (ASP)		**ASP >>>>>> Aspecto**	
	CLARO		CLARO
	LIG. TURB	no conversion required	LIG. TURB
	TURBIA		TURBIA
	MUY TURB		MUY TURB
	OTROS		OTROS
Invalid Result Value	ERROR	no conversion required	ERROR

Support for CLINITEK® 200+ Program D40100

	Spanish with PLUS system set to ON		
Test	**CLINITEK 500**	**>>>>>>>>>>**	**CLINITEK 200+**
Glucose (GLU)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO 1+ 2+ 3+
Bilirubin (BIL)	NEGATIVO 1+ 2+ 3+	no conversion required	NEGATIVO 1+ 2+ 3+
Ketone (CET)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO 1+ 2+ 3+
Specific Gravity (DEN)	<= 1.005 1.010 1.015 1.020 1.025 >=1.030	no conversion required	<= 1.005 1.010 1.015 1.020 1.025 >=1.030
Blood (SAN)	NEGATIVO IND. INTACTOS IND.HEMOLIZ. 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO INDICIO 1+ 2+ 3+
pH (pH)	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	no conversion required	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (PRO)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO 1+ 2+ 3+
Urobilinogen (URO)	0.2 U.E./dL 1.0 U.E./dL 2.0 U.E./dL 4.0 U.E./dL >=8.0 U.E./dL	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite (NIT)	NEGATIVO POSITIVO	no conversion required	NEGATIVO POSITIVO
Leukocytes (LEU)	NEGATIVO INDICIOS 1+ 2+ 3+	>>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>> >>>>>>>>>	NEGATIVO INDICIO 1+ 2+ 3+

Spanish with PLUS system set to ON			
Test	CLINITEK 500	>>>>>>>>>>	CLINITEK 200+
Color (COL)		**COL >>>>>> Color**	
	CL. AMARILLO	>>>>>>>>>>	COLURICA
	AMARILLO	>>>>>>>>>>	AMARILLO
	OSC. AMARILLO	>>>>>>>>>>	AM. OSCURO
	CL. NARANJA	>>>>>>>>>>	AMBAR
	NARANJA	>>>>>>>>>>	ANARANJ
	OSC. NARANJA	>>>>>>>>>>	ANARANJ
	CL. ROJO	>>>>>>>>>>	ROJIZO
	ROJO	>>>>>>>>>>	ROJIZO
	OSC. ROJO	>>>>>>>>>>	ROJIZO
	CL. VERDE	>>>>>>>>>>	VERDOSO
	VERDE	>>>>>>>>>>	VERDOSO
	OSC. VERDE	>>>>>>>>>>	VERDOSO
	CL. AZUL	>>>>>>>>>>	OTROS
	AZUL	>>>>>>>>>>	OTROS
	OSC. AZUL	>>>>>>>>>>	OTROS
	CL. MARRON	>>>>>>>>>>	OTROS
	MARRON	>>>>>>>>>>	OTROS
	OSC. MARRON	>>>>>>>>>>	OTROS
Clarity (CLA)		**ASP >>>>>> Aspecto**	
	CLARO		CLARO
	LIG. TURB	no conversion required	LIG. TURB
	TURBIA		TURBIA
	MUY TURB		MUY TURB
	OTROS		OTROS
Invalid Result Value	ERROR	no conversion required	ERROR

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APPENDIX E – Printer Report Formats   *Return*

Printer Report Formats

This section defines the report formats used for al printed reports. Three different printers are supported: the
CLINITEK 500 internal printer, an 80 column printer and a Form printer. Not all report formats are available for all
printers. Printer selections are made on the "Printer Options" screen

Calibration Confirmation

This report is available from Screen: Report Options.

Printer Priorities:
If both the internal printer and an 80-column printer are set to ON, results are printed on the internal printer.

This report is not available for the Form printer.

Printer Format:

```
line 1   CLINITEK 500
line 2   Calibration Successful
line 3   AAAAAAAA  BBBBBBBB
```

Variable Field Descriptions:

A:	Represents the date of the test. The date is displayed in the date format set onScreen: Protected Setup (2/8).
B:	Represents the time of the test. The time is displayed in the time format set on Protected Setup (2/8).

.

Load List Report

This report is available by pressing the Print button from Scree: Sample ID Entry or Screen: Report Options.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, results are printed on the internal printer.

This report is not available for the Form printer.

Printer Format: There will be a maximum of three lines printed for each entry in the load list and a minimum of one line.

```
line 1   CLINITEK 500
line 2   Load List
line 1   AAA. BBBBBBBBBBBBB CCCC
line 2        DDD EEEEEEEEEEEEEEE
line 3        FFF GGGGGGGGGGGGGGG
line 4   AAA. BBBBBBBBBBBBB CCCC
line 5        DDD EEEEEEEEEEEEEEE
line 6        FFF GGGGGGGGGGGGGGG
```

Variable Field Descriptions:

A:	Represents the position of the ID in the load list.
B:	Represents the ID.
C:	If the ID has been assigned to a test strip, printed as 'Done'; otherwise not printed.
D:	If Color is set to ON on Screen: Tests to Report and Their Order, printed as COL; otherwise this line is not printed.
E:	If Color is set to ON on Screen: Tests to Report and Their Order, printed as the Color value assigned to this test; otherwise this line is not printed.
F:	If Clarity is set to ON on Screen: Tests to Report and Their Order, printed as CLA; otherwise this line is not printed.
G:	If Clarity is set to ON on Screen: Tests to Report and Their Order, represents the Clarity value assigned to this test; otherwise this line is not printed.

Clinical Results format for Patient/Control Results

The same report format is used for patient test results and Control test results. Likewise, the same format is used for printing new test results, printing edited test results, and printing recalled results.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, results are printed on the internal printer.

If both the internal printer and a Form printer are set to ON, new test results, edited test results, and recalled test results are printed on the Form printer.

Internal Printer Format: Although the number of lines between each result set is operator selectable for patient results, there are always two lines between Control results.

Form Printer Format:

```
line  1   AAAAA BBBBBBBB CCCCCCC
line  2   Tech ID: DDD
line  3   ID: EEEEEEEEEEEEE
line  4   FGHHH IIIIIIIIIIIIIII
line  5   FGHHH IIIIIIIIIIIIIII
line  6   FGHHH IIIIIIIIIIIIIII
line  7   FGHHH IIIIIIIIIIIIIII
line  8   FGHHH IIIIIIIIIIIIIII
line  9   FGHHH IIIIIIIIIIIIIII
line 10   FGHHH IIIIIIIIIIIIIII
line 11   FGHHH IIIIIIIIIIIIIII
line 12   FGHHH IIIIIIIIIIIIIII
line 13   FGHHH IIIIIIIIIIIIIII
line 14   FGHHH IIIIIIIIIIIIIII
line 15   FGHHH IIIIIIIIIIIIIII
line 16   JJJJJJJJJJJJJJJJJJJJ
```

Variable Field Descriptions:

A:	Represents the Sequence Number.
B:	Represents the date of the test. The date is displayed in the date format set on Screen: Protected Setup (2/8).
C:	Represents the time of the test. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
D:	Represents the Tech ID. If the "Tech ID" option is set to OFF on Screen: Protected Setup (7/8)., not printed.
E:	Represents the ID. If the "Sample IDs" option is set to OFF on Screen: Protected Setup (7/8)., not printed.
F:	Printed as an asterisk ('*') if the test result is positive; otherwise not printed.
G:	Printed as an exclamation symbol ('!') if the test result has been edited; otherwise not printed.
H:	Represents the test abbreviation.
I:	Represents the test result.
J:	Represents the operator defined header when the Internal Printer option is set to 'ON with 12 blank lines between patient result sets'; otherwise this line is not printed.

One test result line is printed for each test selected to be reported on Screen: Tests Reported and Their Order. The printed order of the tests is the order selected on this screen. Line 16 is only printed if the Internal Printer option is set to 'ON with 12 blank lines between patient result sets.'

80 Column Printer Format: The format for clinical results is a left-aligned triple column format. Line 1 of each page contains the page number of the results report. There is one blank line between result sets. If only one test result is reported, lines 3, 4, and 5 are not printed. If only two test results are reported, lines 4 and 5 are not printed. Results are never printed across the paper perforation. To accommodate the printing restrictions associated with ink jet and laser jet printers, a form feed is issued after line 56 on each page. Form feeds are also issued at the end of the results printed for each RUN.

```
line  1                                                   Page JJJ
line  2     AAAAA  BBBBBBBB  CCCCCCC      Tech ID: DDD     ID: EEEEEEEEEEEE
line  3     FGHHH  IIIIIIIIIIIIIII     FGHHH  IIIIIIIIIIIIIII     FGHHH
IIIIIIIIIIIIIII
line  4     FGHHH  IIIIIIIIIIIIIII     FGHHH  IIIIIIIIIIIIIII     FGHHH
IIIIIIIIIIIIIII
line  5   FGHHH  IIIIIIIIIIIIIII    FGHHH IIIIIIIIIIIIIII    FGHHH IIIIIIIIIIIIIII
line  6     FGHHH  IIIIIIIIIIIIIII     FGHHH  IIIIIIIIIIIIIII     FGHHH
IIIIIIIIIIIIIII
```

The print order for the test results is:

```
      1      5       9
      2      6      10
      3      7      11
      4      8      12
```

Variable Field Descriptions:

A:	Represents the Sequence Number.
B:	Represents the date of the test. The date is displayed in the date format set on Screen: Protected Setup (2/8)..
C:	Represents the time of the test. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
D:	Represents the Tech ID. If the "Tech ID" option is set to OFF on Screen: Protected Setup (7/8)., not printed.
E:	Represents the ID. If the "Sample ID" option is set to OFF on Screen: Protected Setup (7/8)., not printed.
F:	Printed as an asterisk ('*') if the test result is positive; otherwise not printed.
G:	Printed as an exclamation symbol ('!') if the test result has been edited; otherwise not printed.
H:	Represents the test abbreviation.
I:	Represents the test result.
J:	Represents the page number.

Results Not Available Report

The same report format is used for the list of patients for whom results are not available due either to the operator canceling the test RUN or to the test run being terminated by the Analyzer due to a reported error condition.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, results are printed on the internal printer.

This report is not available for the Form printer.

Internal Printer Format: The last line of the report is followed by two blank lines.

80 Column Printer Format: The last line of the report is followed by two blank lines.

Report Format with IDs set to ON

```
line  1      Results Not Available
line  2      AAAAA ID:BBBBBBBBBBBBBBB
line  3      AAAAA ID:BBBBBBBBBBBBBBB
                .
                .
                .
line  n      AAAAA ID:BBBBBBBBBBBBBBB
```

Variable Field Descriptions:

A:	Represents the Sequence Number.
B:	Represents the ID.

Report Format with IDs set to OFF

```
line  1      Results Not Available
line  2      AAAAA
line  3      AAAAA

line  n      AAAAA
```

Variable Field Descriptions:

A:	Represents the Sequence Number.

Confirmatory Report / Microscopics Report

The Confirmatory report lists the patients whose tests have met the Confirmatory flags criteria. The Microscopics report lists the patients whose tests have met the Microscopics flags criteria. The format of the two reports is identical. They are differentiated by their header.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, the report is printed on the internal printer.

This report format is not available for the Form printer.

Internal Printer Format / 80 Column Printer Format:

```
line  1      AAAAAAAAAAAAAAAAAAAA
line  2      BBBBBBBB CCCCCCC
line  3
line  4      DDDDD ID: EEEEEEEEEEEEE
```

```
line  5     FFF   FFF   FFF   FFF   FFF
line  6
line  7     DDDDD ID: EEEEEEEEEEEE
line  8     FFF   FFF   FFF   FFF   FFF
```

Variable Field Descriptions:

A:	Printed as Confirmatory Report or Microscopics Report.
B:	Represents the date of the RUN. The date is displayed in the date format set on Screen: Protected Setup (2/8)..
C:	Represents the time of the RUN. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
D:	Represents the Sequence Number.
E:	Represents the ID. If the "Sample IDs" option is set to OFF on Screen: Protected Setup (7/8)., not printed.
F:	Represents the test which met the report criteria.

Two lines are printed for each patient. One blank line separates patient data.

Results Error Report

The Results Error report lists the samples for which clinical results are not available because an error was reported during the calculation of at least one of the results. This type of an error is not an instrument or system error, it affects only the results of the sample for which the error is reported and does not stop the RUN. This report is displayed after the Confirmatory and Microscopic reports.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, the report is printed on the internal printer.

This report format is not available for the Form printer.

Internal Printer Format / 80 Column Printer Format:

```
line  1      Results Error Report
line  2      AAAAAAAA BBBBBBB
line  3
line  4      CCCCC ID: DDDDDDDDDDDDD
line  5      CCCCC ID: DDDDDDDDDDDDD

line  n      CCCCC ID: DDDDDDDDDDDDD
```

Variable Field Descriptions:

A:	Represents the date of the RUN. The date is displayed in the date format set on Screen: Protected Setup (2/8)..
B:	Represents the time of the RUN. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
C:	Represents the Sequence Number.
D:	Represents the ID. If the "Sample IDs" option is set to OFF on Screen: Protected Setup (7/8)., not printed.

One line is printed for each sample.

System Configuration Report

This report lists the operator selectable options and their current setting.

Printer Priorities:
If both the internal printer and an 80 column printer are set to ON, this report is printed on the 80 column printer.

This report is not available for the Form printer.

Internal Printer Format: The printer advances two lines after the report has been printed.

```
line 1       CLINITEK 500
line 2       System Configuration
line 3       AAAAAAAA BBBBBBB
line 4       Software Version:
line 5       CC.CC/CC.CC
line 6
line 7       User Interface Settings
line 8       Language:
line 9       DDDDDDD
line 10      Result units:
line 11      DDDDDDDDDDDD
line 12      PLUS system:
line 13      DDD
line 14      Date format:
line 15      DDDDDDD
line 16      Test:
line 17      DDDDDDDDDDDDDDDDDDDDDDDD
line 18      Date separator:
line 19      DDD
line 20      Time format:
line 21      DDDDDDD
```

```
line 22     Time separator:
line 23     DDD
line 24
line 25     Test Settings
line 26     Tests to be Reported
line 27     and Their Order:
line 28     EEE*
line 29     EEE*
line 30     EEE*
line 31     EEE*
line 32     EEE*
line 33     EEE*
line 34     EEE*
line 35     EEE*
line 36     EEE*
line 37     EEE*
line 38     EEE*
line 39     Color:**
line 40     DDDDDDDDDDDDDDDDDDDDD
line 41     Color values:**
line 42     DDDDDDDDDDDDDDD (def)
line 43     DDDDDDDDDDDDDDD*
line 44     DDDDDDDDDDDDDDD*
line 45     DDDDDDDDDDDDDDD*
line 46     DDDDDDDDDDDDDDD*
line 47     DDDDDDDDDDDDDDD*
line 48     DDDDDDDDDDDDDDD*
line 49     Clarity values:**
line 50     DDDDDDDDDDDDDDD (def)
line 51     DDDDDDDDDDDDDDD*
line 52     DDDDDDDDDDDDDDD*
line 53     DDDDDDDDDDDDDDD*
line 54     DDDDDDDDDDDDDDD*
line 55     Use Default COL/CLA:
line 56     DDD
line 57     Levels considered pos.:
line 58     EEE DDDDDDDDDDDDDDD*
line 59     EEE DDDDDDDDDDDDDDD*
line 60     EEE DDDDDDDDDDDDDDD*
line 61     EEE DDDDDDDDDDDDDDD*
line 62     EEE DDDDDDDDDDDDDDD*
line 63     EEE DDDDDDDDDDDDDDD*
line 64     EEE DDDDDDDDDDDDDDD*
line 65     EEE DDDDDDDDDDDDDDD*
line 66     EEE DDDDDDDDDDDDDDD*
line 67     SG Lower Normal Limit:**
line 68     DDDDDDD
line 69     SG Upper Normal Limit:**
line 70     DDDDDDD
line 71     pH Lower Normal Limit:**
line 72     DDDDD
line 73     pH Upper Normal Limit:**
line 74     DDDDD
line 75     First Positive Level**
line 76     for COL:**
line 77     DDDDDDDDDDDDDDD
line 78     First Positive Level**
line 79     for CLA:**
line 80     DDDDDDDDDDDDDDD
```

```
line 81      Confirmatory Flags:***
line 82      EEE EEE EEE EEE EEE
line 83      Microscopics Flags:***
line 84      EEE EEE EEE EEE EEE
line 85      Edit flagged results:
line 86      DDD
line 87      Tests Using Altered
line 88      Ranges****
line 89      EEE EEE EEE EEE
line 90      EEE EEE EEE EEE
line 91
line 92      System Settings
line 93      Tech ID:
line 94      DDD
line 95      Sample IDs:
line 96      DDD
line 97      Password for Setup:
line 98      DDD
line 99      Internal printer:
line 100     DDDDDDDDDDDDDDDD
line 101     External printer:
line 102     DDDDDDDDD
line 103     Custom Header:*****
line 104     DDDDDDDDDDDDDDDDDDDDD
line 105     Computer link
line 106     Port:
line 107     OFF
line 108     Baud Rate:
line 109     DDDDDD
line 110     Data Bits/Par.:
line 111     DDDDDD
line 112     Output Format:
line 113     DDDDDD
line 114     Checksum:
line 115     DDDDDD******
line 116     Handshake:
line 117     DDDDDD******
line 118     Label:
line 119     DDD
line 120     Ignore Lead BC Char.:
line 121     0
line 122     Ignore Trail BC Char.:
line 123     0
```

Variable Field Descriptions:

A:	Represents the date of the test. The date is displayed in the date format set on Screen: Protected Setup (2/8)..
B:	Represents the time of the test. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
C:	Represents the Software Versions of the processors.
D:	Represents the current option for a system setting.
E:	Represents a test abbreviation.

*	This line is not printed if the corresponding test is not selected on Screen: Tests to Report and Their Order.
**	The option for this line is printed as 'N/A' if the corresponding test is not selected onScreen: Tests to Report and Their Order.
***	The option for this line is printed as 'None' if no tests are selected for the flag criteria.
****	This option is not printed if Altered Ranges are not in use.

*****	The option for this line is printed as 'N/A' if the Internal Printer option on Screen: Printer Options is NOT set to 'ON with 12 blank lines between patient result sets.
******	The option for this line is printed as 'N/A' if the Output Format is set to 'CT500'.

80 Column Printer Format: The printer issues a form feed after the report has been printed.

```
line  1      System Configuration                         Page FFF
line  2      AAAAAAAA BBBBBBB
line  3      Software Version:  CC.CC/CC.CC
line  4
line  5      User Interface Settings
line  6      Language:       DDDDDDD
line  7      Result units:   DDDDDDDDDDDDDDDDDDDDD
line  8      PLUS system:    DDD
line  9      Test:           DDDDDDDDDDDDDDDDDDDDDDDDD
line 10      Date format:    DDDDDDDD
line 11      Date separator: DDD
line 12      Time format:    DDDDDDD
line 13      Time separator: DDD
line 14
line 15      Test Settings
line 16      Tests to be Reported and Their Order:
line 17      EEE EEE EEE EEE EEE EEE EEE EEE EEE EEE EEE EEE
line 18      Color:  DDDDDDDDDDDDDDDDDDDDDDD**
line 19      Color values:**
line 20      DDDDDDDDDDDDDDD (default)
line 21      DDDDDDDDDDDDDDD*
line 22      DDDDDDDDDDDDDDD*
line 23      DDDDDDDDDDDDDDD*
line 24      DDDDDDDDDDDDDDD*
line 25      DDDDDDDDDDDDDDD*
line 26      DDDDDDDDDDDDDDD*
line 27      Clarity values:**
line 28      DDDDDDDDDDDDDDD (default)
line 29      DDDDDDDDDDDDDDD*
line 30      DDDDDDDDDDDDDDD*
line 31      DDDDDDDDDDDDDDD*
line 32      DDDDDDDDDDDDDDD*
line 33      Use Default COL/CLA:      DDD
line 34      First Positive Level:
line 35      EEE DDDDDDDDDDDDDDD*
line 36      EEE DDDDDDDDDDDDDDD*
line 37      EEE DDDDDDDDDDDDDDD*
line 38      EEE DDDDDDDDDDDDDDD*
line 39      EEE DDDDDDDDDDDDDDD*
line 40      EEE DDDDDDDDDDDDDDD*
line 41      EEE DDDDDDDDDDDDDDD*
line 42      EEE DDDDDDDDDDDDDDD*
line 43      EEE DDDDDDDDDDDDDDD*
line 44      SG Lower Normal Limit:  DDDDDDD**
line 45      SG Upper Normal Limit:  DDDDDDD**
line 46      pH Lower Normal Limit:  DDDDD**
line 47      pH Upper Normal Limit:  DDDDD**
line 48      First Positive Level for COL: DDDDDDDDDDDDDDD**
line 49      First Positive Level for CLA: DDDDDDDDDDDDDDD**
line 50      Flags for Confirmatory Report:  EEE EEE EEE EEE EEE***
line 51      Flags for Microscopics Report:  EEE EEE EEE EEE EEE***
```

```
line 52      Edit flagged results: DDD
line 53      Tests Using Altered Ranges:  EEE EEE EEE EEE EEE EEE EEE EEE****
page break
line  1      System Configuration                         Page FFF
line  2      System Settings
line  3      Tech ID:  DDD
line  4      Sample IDs:  DDD
line  5      Password for Setup:  DDD
line  6      Internal printer:  DDDDDDDDDDDDDDDD
line  7      External printer:  DDDDDDDDD
line  8      Custom Header:  DDDDDDDDDDDDDDDDDDDD*****
line  9      Computer link:
line 10      Port:           DDD
line 11      Baud Rate:      DDDD
line 12      Data Bits/Par.:  DDDDDD
line 13      Output Format:  DDDDDD
line 14      Checksum:       DDD******
line 15      Handshake:      DDD******
line 16      Label: DDD
line 17      Ignore Lead. BC Char.:  D
line 18      Ignore Trail BC Char.:  D
```

Variable Field Descriptions:

A:	Represents the date of the test. The date is displayed in the date format set on Screen: Protected Setup (2/8)..
B:	Represents the time of the test. The time is displayed in the time format set on Screen: Protected Setup (2/8)..
C:	Represents the Software Versions of the processors.
D:	Represents the current option for a system setting.
E:	Represents a test abbreviation.

*	This line is not printed if the corresponding test is not selected on Screen: Teststo Report and Their Order
**	The option for this line is printed as 'N/A' if the corresponding test is not selected on Screen: Tests to Report and Their Order.
***	The option for this line is printed as 'None' if no tests are selected for the flag criteria.
****	This option is not printed if Altered Ranges are not in use.
*****	The option for this line is printed as 'N/A' if the Internal Printer option on Screen: Printer Options is NOT set to 'ON with 12 blank lines between patient result sets.
******	The option for this line is printed as 'N/A' if the Output Format is set to 'CT500'.

Test Mode Results

Test Mode 1 results always print in a set order. An example is:

```
000006     19981006180200
ERRORS: 0000     POS: 43
Tech ID: 1111112222233
ID: 3234567890123
COL    A    B    L    CD
       +851 +113 +265 +000
SRV  I    R    G    B    DCD
GLU 817 310 568 456 1558
BIL 713 588 435 296 0610
KET 734 604 477 331 0649
SG  726 474 398 133 1201
pH  719 486 392 130 0677
PRO 695 273 332 235 0435
URO 719 735 538 143 0747
NIT 697 606 288 280 0476
BLO 126 123 123 125 0124
LEU 608 442 279 244 1000
LE1 653 486 311 262 0477
```

Test Mode 2 results print Test Mode 1 results format, a blank line, and then the list of test labels and clinical result values. The clinical result portion of the printout is in the order as set by the Tests to Report and Their Order option.

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APPENDIX F – Result Mode Format and Altered Ranges   *Return*

F.1   Result Format - Test Mode 2

Introduction

CLINITEK® 500 Urine Chemistry Analyzer Customers who choose to alter instrument ranges should collect data from a statistically significant number of samples for comparison to the reference method(s). Setting the instrument in Test Mode 2 adds a printout of raw decode data above each set of test results.

NOTE

By design, choosing Test Mode 2 disables the computer port and turns the internal printer OFF. The computer port cannot be enabled. The printer can be selected back ON in Printer Setup.

Procedure

1. From the Ready/Run screen, touch the "Menu" option.

2. From the Menu screen, touch the "Setup" option.

3. Press the ▷ key seven (7) times to display Setup Menu #8 with "Computer Port Options" as the first selection.

4. Touch the "Computer Port Options" key to display the computer port options screen.

5. See Figure. On this screen, there is a special "Hidden Key" which is located below the "Set" of the "Set options" screen header and above the "Port - ON/OFF" key.   Pressing the screen in this area two times (2X) displays a fifth option.

6. The fifth option, "Results Format", will display. The default format is "Clinical Values". The selections are shown as "EEEEEEEEEEE" in the figure. Press the key again to cycle through Test Mode 1, Test Mode 2 and/or back to Clinical Values. For data review purposes, choose Test Mode 2. Each test strip's results will print to the internal printer as raw data and as clinical results.

7. Press the ◁ key eight (8X) times to return to printer setup screen. Select the Internal printer back to ON**.**

Hidden Key Access to Result Format

F.2 Altered Ranges

Introduction

The CLINITEK® 500 Urine Chemistry Analyzer offers the customer the ability, if desired, to customize sensitivity of the clinical ranges of certain tests. This function allows the customers to actually adjust the upper limit for each clinical range thus altering the sensitivity of the instrument. The tests to which this feature applies are the following:

- Glucose
- Ketone
- Bilirubin
- Blood
- Protein
- Urobilinogen
- Leukocytes

CAUTION

If a customer elects to use this option and adjusts the range for any analyte, the performance characteristics stated by Bayer for that analyte are no longer valid. Validation of the new ranges and expected results become the responsibility of the user.

Procedure

1. From the Ready/Run screen, touch the "Menu" option.

2. From the Menu screen, touch the "Setup" option. Press the ▷ key eight times (8X) to advance to the last "Set Options" screen. See Figure.

3. On this screen, there is a special "Hidden Key" which is located under the "Set" of the Set Options screen header and above the "Reset all features to defaults" key. Pressing the screen in this area two times (2X) displays a third option, "Alter test ranges". See figure.

Hidden Key Not Pressed

Set options.

Reset all features to defaults

Perform hardware tests

Hidden Key 2X

Set options.

Reset all features to defaults

Perform hardware tests

Alter test ranges

Hidden Key Access to Altered Ranges

4. Touch the "Alter test ranges" option. The screen will display the tests that can be altered. The test names are indicated by a three-letter abbreviation given in the figure below as "AAA".

Return to Ready/Run

```
Select test to alter its
clinical ranges.                    ⛛

   [●] AAA         [●] AAA          ☰

   [●] AAA         [●] AAA

   [●] AAA         [●] AAA

   [●] AAA         [●] AAA          ◀
```

Altered Ranges -- Select Test Screen

```
Alter ranges for AAA.                ⛛
Use ⬆ and ⬇to select range.
Use "+" and "-" to adjust, then
press ↵to accept.

 BBBBBBBBBBBBBBBB  CCCC    [+]   [⬆]
 BBBBBBBBBBBBBBBB  CCCC
 BBBBBBBBBBBBBBBB  CCCC    [-]   [⬇]
 BBBBBBBBBBBBBBBB  CCCC
 BBBBBBBBBBBBBBBB  CCCC

   [C]Use defaults-DDD     [↵]   [◀]


EEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEEE
```

Altered Ranges -- Adjust Test Screen

5. Touch the key next to the test to be altered.
The display will change to show the clinical level, such as "Negative, Trace, 100 mg/dL, 250 mg/dL, 500 mg/dL, and >= 100 mg/dL."
The fields "CCCC" indicate the upper limit for the specific clinical level.

6. Ranges can be altered ONLY if the "Use defaults" key is toggled to "ON".

IMPORTANT

- Increasing the limit by using the "+ " key will *decrease* the instrument's sensitivity.
For example, increasing the "NEGATIVE" decodes for BLO (blood) will reduce the number of "trace blood" urines.

- Decreasing the limit using the "-" key will *increase* the instrument's sensitivity.

7. Use the up or down arrow key to select a level. Then use use the + and – keys to change the range.

8. After completing all desired clinical range adjustments, press the "Return to Ready Run" key to save the changes to the configuration.

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CLINITEK Communication Standard

1. Introduction

Today it is the rare exception rather than the norm when a clinical instrument is designed with no provision for connection to a laboratory computer system. Without some kind of standardization or "rules for operation", the communication interface between each new instrument and each laboratory computer system is more than likely to be different. This lack of standardization increases the time and costs both to produce the instrument and to successfully establish a communication link with a laboratory computer system. In an effort to provide a "plug and play" compatibility for future Bayer CLINITEK® instruments with laboratory computer systems, Urine Chemistry Diagnostics at Bayer Corporation is standardizing the communication interface its CLINITEK instruments will use to communicate with laboratory computer systems.

This specification defines the data codes, transmission protocol, error recovery and message content for the information that passes between a Bayer CLINITEK7 Urine Chemistry instrument and a laboratory computer. Beginning with the introduction of the CLINITEK7 500 Urine Chemistry Analyzer, all CLINITEK Urine Chemistry instruments will support the new communication interface defined by this specification. This new interface is called the CLINITEK7 Communication Standard (CCS).

The CCS fully supports ASTM Specification E1381, *Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems*. The CCS supports ASTM Specification E1394, *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems* with some modifications to the types of fields supported within the various record formats. The CCS supports the following ASTM record types: Header records (H), Manufacturing records (M), Patient records (P), Result records (R), Test Order records (O), Request Information records (Q), Comment records (C), and Message Termination records (L). Not all records types are supported by every instrument. Bayer Urine Chemistry Diagnostics will issue a communication specification for each new instrument which details the record types supported and defines the format and content of all instrument specific fields.

2. Terminology

Download - Download is the transfer of data from a computer system to a clinical instrument.

Field - A field is the smallest element of information in any record. It contains a single item of information, such as a date, sample ID, or a numeric test result.

Component Field - A component field is an item of information that can be further divided into parts or components. As an example, the result for a test is stored as the numeric value and the unit of measure label separated by a component delimiter.

Frame - A frame is a subdivision of a message. It is used to allow periodic communication housekeeping such as error checks and acknowledgments.

Message - A message is a collection of related information. It is a textual body of information. A message is all the information sent during one session. Messages can consist of many different types of records.

Receiver - The receiver is the device that responds to the sender and accepts the message.

Record - A record is an aggregate of fields describing one aspect of the complete message.

Session - A session is a total unit of communication activity. A session starts with the establishment phase and ends with the termination phase.

Sender - The sender is the device that has a message to send and initiates the transmission process.

Test - A test is the determination of a single chemistry pad. Our urine chemistry reagent strips have multiple pads on them. For example, a MULTISTIX 10 SG test strip reports the results of 10 tests.

Upload - Upload is the transfer of data from a clinical instrument to a computer system.

3. Low Level Protocols

3.1　　Physical Layer

The physical layer is the mechanical and electrical connection for serial binary data bit transmission between the CLINITEK instrument and laboratory computer system. The topology is point-to-point, a direct connection between two devices.

The receiver is the device that responds to the sender and accepts the message. Either the CLINITEK instrument or the laboratory computer system may be the receiver. The sender is the device that has a message to send and initiates the transmission process. Either the CLINITEK instrument or the laboratory computer system may be the sender.

A session is a total unit of communication activity. A session begins with the establishment of communication between the CLINITEK instrument and the laboratory computer and ends with the termination of communication between the CLINITEK instrument and the laboratory computer.

3.1.1　Character Structure

The method of data transmission is serial-by-bit start/stop. The order of the bits in a character is:
　　　a.　　One start bit, corresponding to a binary 0.
　　　b.　　The data bits of the character, least significant bit being transmitted first.
　　　c.　　Parity bit.
　　　d.　　Stop bit(s), corresponding to a binary 1.

The time between the stop bit of one character and the start bit of the next character may be of any duration. The data interchange circuit is in the marking condition between characters.

The default character structure consists of one start bit, eight data bits, no parity bit, and one stop bit. Other character structures are supported, for example, seven data bits and odd parity or seven data bits and even parity.

The character bit sequencing, structure, and parity sense definitions confirm to ANSI standards X3.15-1976 and X3.16-1976.

3.1.2 Electrical Characteristics

The voltage and impedance levels for the generator and receiver circuits conform to the EIA-232-D-1986 standard.

3.1.3 Interface Connections

The CCS supports the connector requirements of ANSI standard E1381-91.

3.1.4 Signal Levels

For the data interchange circuits, a marking condition corresponds to a voltage more negative than minus three volts with respect to signal ground at the interface point. A spacing condition corresponds to a voltage more positive than plus three volts with respect to signal ground at the interface point.

Binary state ONE (1) corresponds to the marking condition; binary state ZERO (0) corresponds to the spacing condition.

The signal levels conform to the EIA-232-D-1986 standard.

3.1.5 Speed

The default data transmission rate is 9600 baud. The data transmission rates supported are 2400, 4800, 9600, and 19200.

3.2 Data Link Layer

The data link layer contains the procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery.

The CCS is a simple data link protocol. The data link protocol is designed for sending character based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.   (See Section 4 Record Structure and Content on page 10 for a list of restricted characters.)

The data link mode of operation is a one-way transfer of information with alternative supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simplex stop-and-wait protocol.

At times both systems are actively operating to transfer information - one side sending and the other side receiving. The remainder of the time the data link is in a neutral state waiting for one of the sides to request control.

There are three distinct phases in transferring information between the CLINITEK instrument and a laboratory computer system. In each phase, one side directs the operation and is responsible for continuity of communication. The three distinct phases assure the actions of sender and receive are coordinated. The three phases are:

1.   Establishment Phase (Link Connection)

2.   Data Transfer Phase

3.   Termination Phase (Link Release)

3.2.1 Establishment Phase (Link Connection)

The establishment phase determines the direction of information flow and prepares the receiver to accept information. The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the **<ENQ>** transmission control character to the intended receiver.

Upon receiving the **<ENQ>**, the receiver must respond to the sender before the sender can begin sending information. If the receiver is able to receive information, it responds with an **<ACK>** transmission control character signifying that it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

If the receiver cannot immediately receive information from the sender, the receiver replies with a **<NAK>** transmission control character. Upon receiving **<NAK>**, the sender must wait at least 10 seconds before again attempting to establish a communication link by transmitting another **<ENQ>**. If both systems simultaneously attempt to start a communication session by transmitting an **<ENQ>**, the data link is considered to be in contention. The CLINITEK instrument has priority to transmit information when contention occurs. The contention to start a communication session is resolved as follows:

Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the computer system must stop trying to transmit; it must prepare to receive. The computer sets a timer. If an **<ENQ>** is not received from the CLINITEK instrument within 20 seconds, a time-out occurs. After a time-out, the receiver regards the line to be in the neutral state and may again attempt to acquire the line by sending an **<ENQ>** to the CLINITEK instrument. If, however, the computer receives an **<ENQ>** from the CLINITEK instrument within the 20 second period, it must reply with an **<ACK>** or **<NAK>** depending on its readiness to receive information.

Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the CLINITEK instrument must wait at least 1 second before sending another **<ENQ>**.

3.2.2 Transfer Phase

During the transfer phase, the sender transmits messages to the receiver. The transfer phase continues until all the messages have been sent.

3.2.2.1 Frames

Each message is sent in a series of frames. A frame is a pre-defined subdivision of a message used to provide for periodic communication housekeeping such as error checks and acknowledgments. Each frame contains a maximum of 247 characters (including frame overhead). Messages longer than 240 characters are divided between two or more frames. Both the sender and receiver must be able to buffer one complete frame (247 characters).

Multiple messages are never combined in a single frame. Every message must begin in a new frame. Records are never split across frames.

A frame is one of two types, an intermediate frame or an end frame. Intermediate frames terminate with the characters **<ETB>**, checksum, **<CR>** and **<LF>**. End frames terminate with the characters **<ETX>**, checksum, **<CR>** and **<LF>**. Messages less than 240 characters may be sent in one end

frame. Longer messages are sent in intermediate frames with the last part of the message sent in an end frame.

The frame structure is as follows:

<STX> FN text **<ETB>** C1 C2 **<CR> <LF>** <-- intermediate frame
.
.
<STX> FN text **<ETX>** C1 C2 **<CR> <LF>** <-- end frame

where:

<STX>	Start of Text transmission control character
FN	single digit Frame Number 0 to 7
text	Data Content of Message
<ETB>	End of Transmission Block transmission control character
<ETX>	End of Text transmission control character
C1	most significant character of checksum 0 to 9 and A to F
C2	least significant character of checksum 0 to 9 and A to F
<CR>	Carriage Return ASCII character
<LF>	Line Feed ASCII character

3.2.2.2 Frame Number

The frame number allows the receiver to distinguish between new and retransmitted frames. IT is a single digit sent immediately after the **<STX>** character.

The frame number is an ASCII digit ranging from 0 to 7. The frame number begins at 1 with the first frame of the Transfer phase. The frame number is incremented by one for every new frame transmitted. After 7, the frame number rolls over to 0, and continues in this fashion.

3.2.2.3 Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters which are sent after the **<ETB>** or **<ETX>** character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the sum.

The checksum is initialized to zero with the **<STX>** character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include **<STX>**, the checksum characters, or the trailing **<CR>** and **<LF>**.

The checksum is an integer represented by eight bits, it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

For example, a checksum of 122 can be represented as 01111010 in binary or 7A in hexadecimal. The checksum is transmitted as the ASCII character 7 followed by the character A.

3.2.2.4 Acknowledgments

The sender sends one frame at a time. After a frame is sent, the sender stops transmitting until a reply is received. When the sender has transmitted the last character of a frame, it sets a timer. The receiver must reply to each frame sent within 15 seconds. If the sender has not received an **<ACK>**, a **<NAK>**, or an **<EOT>** in response to the frame sent within the 15 second time period, the sender enters the termination phase of the communication session by sending an **<EOT>**.

A reply of **<ACK>** from the receiver signifies the frame was received successfully and the receiver is prepared to receive another frame. The sender then increments the frame number and sends the next frame or terminates the communication session.

A reply of **<NAK>** from the receiver signifies the frame was not successfully received and the receiver is prepared to receive the frame again. Upon receiving a **<NAK>** in response to a frame, the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not accepted six times, the sender stops attempting to send the frame and proceeds to the termination phase of the communication session by sending an **<EOT>**.

A reply of **<EOT>** from the receiver tells the sender the frame was received successfully but does not want to continue the communication session. It is a request to the sender to stop transmitting. After receiving the receiver interrupt request, the sender sends the Message Terminator record and ends the communication session.

During the transfer phase, if the receiver responds to a frame with an **<EOT>** in place of the usual **<ACK>**, the sender interprets this reply as a receiver interrupt request. The **<EOT>** is a positive acknowledgment of the end frame <u>and</u> also a request to the sender to stop transmitting.

The sender then enters the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

If the receiver requests the sender stop transmitting results before all the result records have been sent and acknowledged for a patient, ALL the results for that patient must be retransmitted the next time results are sent. If the receiver requests the sender stop transmitting results after the last result is sent for a patient, the next result transmission begins with the next patient record.

3.2.3 Termination Phase (Link Release)

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent.

The sender transmits the **<EOT>** transmission control character and then regards the data link to be in a neutral state. Upon receiving **<EOT>**, the receiver also regards the data link to be in the neutral state.

3.2.4 Error Handling

A receiver checks every frame to guarantee it is valid. A reply of **<NAK>** is transmitted for invalid frames. Upon receiving the **<NAK>**, the sender must retransmit the last frame with the same frame number.

Any characters occurring before the **<STX>** or after the end of the block character (the **<ETB>** or **<ETX>**) are ignored by the receiver when checking the frame.

The receiver should reject a frame when:

- a character error is detected (parity error, framing error, etc.)
- the frame checksum sent does not match the checksum computed on the received frame
- the frame number is not the same as the frame number for a previously rejected frame or the frame number is not one higher than the last accepted frame (modulo 8).

Upon receiving a **<NAK>**, the sender increments a retransmit counter and retransmits the frame. If the retransmit counter shows a single frame was sent and not accepted six times, the sender must abort the message by proceeding to the termination phase.

3.2.5 Timeouts

The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

During the establishment phase, the sender sets a timer when transmitting the **<ENQ>**. If a reply of an **<ACK>**, **<NAK>**, or **<ENQ>** is not received within 15 seconds, a timeout occurs. After a timeout, the sender enters the termination phase.

During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an **<ENQ>** is not received within 20 seconds, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive transmission of defective frames, the message must be retained so that it can be completely retransmitted.

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

A receiver must reply to a frame within 15 seconds or the sender will abort the message and a time out occurs.

4. Record Structure and Content

This part of the specification defines the conventions for structuring the content of the records and for representing the data elements contained within those structures.

A message consists of a hierarchy of records of various types. The following types of records are supported by the CCS:

- Message Header Record
- Message Terminator Record

- Request Information Record
- Order Record
- Patient Record
- Result Record
- Comment Record
- Manufacturer Record

All message data is represented as eight bit values within the range (0-126) as defined by the ASCII standard (ANSI X3.4-1986). None of the ten transmission control characters, the **<CR>** and **<LF>** format control characters, or four device control characters may appear in message text. The CCS format also reserves the **<BEL>** character. The restricted characters are:

Character	ASCII Value	HEX Value
<SOH>	001	01
<STX>	002	02
<ETX>	003	03
<EOT>	004	04
<ENQ>	005	05
<ACK>	006	06
<BEL>	007	07
<LF>	010	0A
<CR>	013	0D
<DLE>	016	10
<DC1>	017	11
<DC2>	018	12
<DC3>	019	13
<DC4>	020	14
<NAK>	021	15
<SYN>	022	16
<ETB>	023	17

Within text data fields, only the ASCII characters 32-126 are permitted as usable characters with the exception of those characters used as delimiter characters. All characters used as delimiters are excluded from the permitted range. The sender is responsible for screening all text data fields to ensure that the text does not contain those delimiters. The contents of the data fields is case sensitive.

Fields are identified by their position within a record. The position is obtained by counting field delimiters from the front of the record. This position-sensitive identification process requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the ith field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields; that is, if the tenth field was the last field containing data, the record could terminate after the tenth field, and therefore would contain only nine delimiters.

The following message delimiters are used for each record:

Delimiter	Character Representation	Definition

Delimiter	Character Representation	Definition
Record Delimiter	Carriage Return <CR> (ASCII 13)	The record delimiter marks the end of each record.
Field Delimiter	Vertical Bar (|) (ASCII 124)	The field delimiter is used to separate adjacent fields.
Repeat Delimiter	Backslash (\\) (ASCII 92)	The repeat delimiter is used to separate variable numbers of descriptors for fields containing parts of equal members of the same set.
Component Delimiter	Caret (^) (ASCII 94)	The component delimiter is used to separate data elements within a field.
Escape Delimiter	Ampersand (&) (ASCII 38)	The escape delimiter is used within text fields to signify special case operations. Applications of the escape delimiter are optional and may be used or ignored at the discretion of either the transmitter or the receiver. All applications must accept the escape delimiter and use it to correctly parse fields within the record.

Transmitted records may include more fields than are required by the receiving system. When processing a record, the receiving system may ignore any field it does not require. All fields in a record are always transferred, and the fields are always transferred in the positional order specified to facilitate accurate identification by the computer system.

This position-sensitive identification procedure requires that when the content of the field is null, its corresponding field delimiter must be included in the record to ensure that the *ith* field can be found by counting (*i* - 1) delimiters. Delimiters are not included for trailing null fields: that is, if a record contains 12 fields and the tenth field is the last field containing data, the record could terminate after the tenth field, and therefore would contain only nine delimiters.

All fields in records are variable length fields.

For all record types, dates are recorded in YYYYMMDD format and times are represented as HHMMSS. Date and time together are specified as a fourteen character string: YYYYMMDDHHMMSS.

4.1 Message Header Record (H)

The Message Header record marks the beginning of a message. It contains information about the sender and identifies the Bayer instrument. It also defines the field, repeat field, component field, and escape delimiter characters. It is ALWAYS the first record sent in a message.

Message Header Record Format

1	2	3	4	5	6	7	8

Record Type	Delimiter Definition	Message Control ID	Access Password	Sender Name	Sender Street Address	Reserved Field	Sender Telephone Number

9	10	11	12	13	14	15
Characteristics of Sender	Receiver ID	Comments	Processing ID	Version No.	Date & Time of Message	<CR>

Example of Message Header Record

H | \^& | | | BAYER^6470 ^^00.20/XP.11 | | | | | | 010 | P | 1| 19970526102030 <CR>

Field Definitions

Record Type
The Record Type is H for a Header Record.

Delimiter Definition
The five ASCII characters that immediately follow the Record Type (H) define the delimiters used for all record types. The second character in the header is the field delimiter (|), the third character in the header is the repeat delimiter (\), the fourth character is the component delimiter (^), and the fifth character is the escape delimiter (&).

Message Control ID
The Message Control ID field holds a unique number or other ID that identifies the transmission for use in network systems that have defined acknowledgment protocols that are outside the scope of ASTM Specification E1394. CCS does not use this field. Its position is represented by the field delimiter.

Access Password
This field is used for a password as mutually agreed upon by the sender and receiver. CCS does not use this field. Its position is represented by the field delimiter.

Sender Name
The Sender Name field is a component field. It defines the manufacturer, the instrument product code, the serial number, and the software version. The manufacturer name is the first component. The instrument product code is the second component. The manufacturer name and the instrument product code are required. The third component is the serial number. The serial number is an optional component. If the serial number component is not used, its position is represented by the component delimiter. The fourth component is the software version. The software version is a required component.

Sender Street Address
This field is for the sender's street address. CCS does not use this field. Its position is represented by the field delimiter.

Sender Telephone Number
This field is for the sender's telephone number. CCS does not use this field. Its position is represented by the field delimiter.

Characteristics of Sender
This field contains any characteristics of the sender such as parity, checksums, optional protocols, etc. necessary for establishing a communication link with the sender. Since this information is normally provided in the Bayer instrument's setup routine, this field will not always contain information and may be represented by the field delimiter.

Receiver ID
This field includes the name or other ID of the receiver. It is used to verify that the transmission is indeed being received by the intended party. CCS does not use this field. Its position is represented by the field delimiter.

Comments or Special Instructions

This field is a component field. Currently there is one component defined. The first component contains the language/result unit code.

Language/Result Unit Codes				
English Conventional-Normal	010		German SI-Normal	070	
English Conventional-PLUS System	011		German SI-PLUS System	071	
English SI-Normal	020		Italian-Normal	080	
English SI-PLUS System	021		Italian-PLUS System	081	
English Nordic-Normal	030		Japanese-Normal	090	
English Nordic-PLUS System	031		Japanese-PLUS System	091	
French Conventional-Normal	040		Spanish-Normal	100	
French Conventional-PLUS System	041		Spanish-PLUS System	101	
French SI-Normal	050		Chinese-Normal	110	
French SI-PLUS System	051		Chinese-PLUS System	111	
German Conventional-Normal	060		Portuguese-Normal	120	
German Conventional-PLUS System	061		Portuguese-PLUS System	121	

Processing ID

This field indicates how this message is to be processed:

● P for Production:

This software has passed all validation criteria and has been production released. The test results may be relied upon for clinical use.

● T for Training:

This software has been released for training purposes only. Test results obtained from this software are not for clinical use.

● D for Debugging:

This software has been released for debugging/testing purposes only. Test results obtained from this software are not for clinical use.

● Q for Quality Control:

This software has been released for the purpose of obtaining quality assurance or regulatory data. Although the portions of the software that collect and process the data have been validated, the test results obtained from this software are not for clinical use.

Version Number

This value identifies the version level of the CLINITEK® Communication Standard Specification. This value is currently one (1).

Date and Time of Message Transmission

This field contains the date and time this header record was sent. The format for this field is YYYYMMDDHHMMSS.

4.2 Message Terminator Record (L)

The Message Terminator record marks the end of the message. It is ALWAYS the last record sent in a message.

Message Terminator Record Format

1	2	3	4
Record	Record	**Termination**	**<CR>**

Type	Sequence Number	**Code**	

Example of Message Terminator Record

L | 1 | N <CR>

or

L | 1 <CR>

Field Definitions

Record Type
The Record Type is L for a Message Terminator record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message. Since there is only one Message Terminator record per message, this field ALWAYS has a value of 1.

Termination Code
The Termination Code provides an explanation for the reason the message ended. The valid Termination Codes are:

null field or N - normal termination
T - sender aborted
R - receiver requested abort
E - unknown system error
Q - error in last request for information
I - no information available from last query
F - last request for information processed

4.3 Request Information Record (Q)

The Request Information record is used by the computer system to request that the receiver identify itself by sending its Message Header record.

Request Information Record Format

1	2	3
Record Type	Record Sequence Number	**<CR>**

Example of Request Information Record

Q | 1   <CR>

Field Definitions

Record Type
The Record Type is Q for a Request Information Record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

4.4 Order Record (O)

The Order record is sent by the computer system to the instrument. It is used to provide the instrument with a list of sample IDs for which tests will be run. Depending on the instrument, this record may also support the inclusion of additional data such as physical descriptions for the color and clarity of the sample. If additional information is supported, the Patient Identification field becomes a component delimited field with each piece of information separated by the component delimiter. Not all CLINITEK instruments support the Order record.

Order Record Format

1	2	3	4
Record Type	Record Sequence Number	Patient Identification	**<CR>**

Example of Order Record for Instrument Accepting only ID Information

0 | 1 | 078302465 <CR>

Example of Order Record for Instrument Accepting ID, Color, and Clarity Information

0 | 1 | 078302465^YELLOW^CLEAR <CR>

Field Definitions

Record Type
The Record Type is O for an Order record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Patient Identification
The Patient Identification field is a component field. At a minimum, it contains the Sample ID for a patient. If the instrument supports additional information such as sample color and clarity, this field is a component delimited field containing all three pieces of information.

4.5 Patient Record (P)

This record contains information about a sample that applies to every Result record for that sample.

Patient Record Format

1	2	3	4	5	6	7	8
Record Type	Record Sequence Number	Test Sequence Number	Date and Time	Sample ID	Tech ID	Sample Location	<CR>

1	2	3	4	5	6	8	9	10

Record Type	Record Sequence Number	Results Format	Test Mode	Test Strip ID	Transfer Status	Error Code	Auxiliary Information	<CR>

Example of Patient Record

P | 1 | 00001 | 19970526102000 | 312432216 | 34010 <CR>

P | 2 | C | P | MULTISTIX 10 SG | F | 0000 | 3^3 <CR>

Field Definitions

Record Type
The Record Type is P for a Patient Record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Test Sequence Number
The Test Sequence Number field holds the sequence number assigned to this test strip by the instrument. The actual format of the sequence number is instrument dependent.

Date and Time
This field contains the date and time of the test. The moment at which the date and time are recorded is instrument dependent. That is, for some instruments, this field represents the date and time the test strip was read at the first readhead. For other instruments, this field may represent the date and time the test was either begun or ended. The format for this field is YYYYMMDDHHMMSS.

Sample ID
This field is optional and is instrument dependent. If this field is not supported by the instrument or if no Sample ID was entered for this test, this field will be empty. If the Tech ID option is set to ON, a field delimiter is used to mark the position of this field.

Tech ID
This field is optional and is instrument dependent. If this field is not supported by the instrument, this field will be empty. If the instrument supports the next field, the Sample Location field, a field delimiter will be used to mark this empty field. If the instrument does support either the Tech ID field or the Sample Location field, a field delimiter is not needed to mark the position of this field if it is empty.

Sample Location
This field is optional and is instrument dependent. If this field is not supported by the instrument, this field will be empty. Since this is the last field in this record, a field delimiter is not needed to mark the position of this field if it is empty.

Results Format
This field holds the code for the output format of the results. There are three options for the Results Format:
● C for Clinical Results Format
● T1 for Test Mode 1 Format

- T2 for Test Mode 2 Format

Test Mode
The Test Mode field defines the type of test being run. There are four options for the Test Mode:
- P for Patient
- S for STAT
- C for Control
- K for Calibration

The Test Mode options are instrument dependent. That is, all instruments do not support all four types of Test Modes.

Test Strip ID
The Test Strip ID field defines the type of reagent test strip used for the test. This field is instrument dependent.

Transfer Status
The Transfer Status field has two options: F for First Time Transfer or R for User Requested Resend.

Error Code
The Error Code field always contains a value. If valid results were able to be calculated for the test strip, the Error Code field contains a value of 0. If a problem was detected which prevents Clinical result values being reported, this field contains a code which defines the source of the problem. The error code values are instrument dependent. This field may be a component delimited field if the instrument supports additional error code detail.

Auxiliary Test Information
The Auxiliary Test Information field is instrument dependent. It may be a component delimited field. If this field is not supported by the instrument, this field will be empty. Since this is the last field in this record, a field delimiter is not needed to mark the position of this field if it is empty.

4.6 Result Record (R)

Each Result record contains the result of a single test determination. Because our urine chemistry test strips contain multiple chemistry tests, there will be one Result record for each result reported. If Color and/or Clarity are also reported, each of these physical results will also be contained in a separate record.

A result record may never appear without a preceding patient record.

Result Record Format

1	2	3	4	5	6	7
Record Type	Record Sequence Number	Test Result Status	Test Name Abbreviation	Test Number ID	Test Result Value and Result Unit of Measure	Clinical Result Level

8	9	10	11
Altered Decode Status	Result Origin	Auxiliary Test Information	<CR>

Example of Result Record for Clinical Results

R | 1 | N | PRO | 6 | 100 ^ mg/dL | 4 | 0 | A <CR>

Example of Result Record for Test Mode 2 Results

R | 1 | N | PRO | 6 | 100 ^ mg/dL | 4 | 0 | A | 413^264^264^200^0639 <CR>

R | 1 | N | PRO | 6 | 100 ^ mg/dL | 4 | 0 | A <CR>

Field Definitions

Record Type
The Record Type is R for a Result Record.

Record Counter
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Test Result Status
The Test Result Status field stores code which defines whether the result is considered normal or abnormal. If the result is within the normal range for the test, this field contains an N. If the test result is outside the normal range for the test, this field contains an A.

Test Name Abbreviation
This field contains the abbreviation for the test pad or physical value. The abbreviations are language dependent.

Test Identification Number
The Test Identification Number field contains a numeric value for the test. Assigning a numeric value for each test provides a non-language dependent identifier for later data analysis.

Test	Numeric ID
Glucose(GLU)	1
Bilirubin (BIL)	2
Ketone (KET)	3
Specific Gravity (SG)	4
Occult Blood (BLO)	9
pH (pH)	5
Protein (PRO)	6
Urobilinogen (URO)	7
Nitrite (NIT)	8
Leukocytes (LEU)	10
Color	11
Clarity	12

Test Result Value ^ Result Unit of Measure
This field contains the clinical test result divided into a numerical component and a result unit of measure component. If the test result is a one word result such as POSITIVE, NEGATIVE, CLEAR, or YELLOW, that result is positioned in the Test Result Value component of the field. For one word results, no component delimiter is used since the Result Unit of Measure portion of the field is empty. For color and clarity results, no component delimiter is used.

Clinical Result Level
The Clinical Result Level field holds the level of the result with respect to the total number of reportable clinical result levels for the test. A level of 1 is always assigned to the lowest or NEGATIVE test value. For example, assume there are five result levels for a chemistry test:

1. NEGATIVE
2. TRACE
3. 30 mg/dL
4. 100 mg/dL

5. >=300 mg/dL

Since the value of 100 mg/dL is the 4th result level, the value assigned to the Clinical Result Level field would be 4.

Altered Decode Status
The Altered Decode Status field contains a 0 if altered decodes are not used. This field contains a 1 if altered decodes are used.

Result Origin
The Result Origin field contains the code which defines the source of the test result. If the result was calculated by the Analyzer, the value of this field is A. If the result was manually entered, the value of this field is M. If the result was edited, the value of this field is E. When Result Records report Clinical Results, this is the last field in the record.

Auxiliary Information
The Auxiliary Information field is not used for Clinical Result records (Result Records for a Patient Record with a value of 'C' in the Test Mode field).   The Auxiliary Information field is used for Test Mode records (Result records for a Patient record with a Results Format value of 'T1' or 'T2').   This field is a component delimited field. The content of the field is instrument dependent.

4.7 Comment Record (C)
A comment record may follow any record but the Message Terminator record. A comment record provides additional information about the previous record. It always relates to the immediately preceding record. Not all CLINITEK instruments support the Comment record.

Comment Record Format

1	2	3	4
Record Type	Record Sequence Number	**Comment Text**	**<CR>**

Example of Comment Record

C | 1 | This is a comment. <CR>

Field Definitions

Record Type
The Record Type is C for a Comment Record.

Record Sequence Counter
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Comment Text
The Comment Text field is instrument dependent. It is not supported by all instruments.

4.8 Manufacturer Record (M)
This record is used to send information for research and development and maintenance use. The content of the Manufacturer Information field varies by instrument.

Manufacturer Record Format

1	2	3	4
Record Type	Record Sequence Number	**Manufacturer Information**	**<CR>**

Example of Manufacturer Record

M | 1 | FAT^I^R^G^B <CR>

Field Definitions

Record Type
The Record Type is M for a Manufacturer Record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Manufacturer Information
This is a component delimited field. The content of the field is instrument dependent.

5. Communication Session Support

The CCS supports three types of communication sessions: a Request for Identification session, an Order session, and a Results Reporting session.

5.1 Request for Identification Communication Session

The Request for Identification communication session is initiated by the laboratory computer. Two different types of sessions are supported: a standard ASTM messaging session and a simple, single character message session.

Standard ASTM Messaging Session
This type of session uses two types of messages: the Request Information Message sent by the laboratory computer and the Identification Message sent by the Analyzer.

The logical structure of the **Identification Request Message** sent by the laboratory computer is:

I**dentification Request Message**
      Message Header Record
         Request Information Record

Note that there is NO Message Terminator record sent after the Request Information record. The receiver is responsible for sending the Message Terminator after replying to the Request Information query.

The logical structure of the **Identification Message** response sent by the Analyzer is:

Identification Message

Message Header Record
Message Terminator Record

If transmission is terminated prior to the Message Terminator record sent by the Analyzer being received and acknowledged, the entire message must be retransmitted in a new session.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Send ENQ to acquire the line
Acknowledge ENQ	→	
	←	Send Header record
Acknowledge Header record	→	
	←	Send Request for Identification record
Acknowledge receipt of Request for Identification record	→	
Send Identification (Header) record	→	
	←	Acknowledge Identification (Header) record
Send Message Termination record	→	
	←	Acknowledge Message Termination record
	←	Send EOT to release the line

Single Character Identification Request Session
This type of session uses the **<BEL>** character to request the Identification Message be sent by the instrument.

The logical structure of the **Single Character Identification Request Session** sent by the laboratory computer is:

I**dentification Request Message**
        <BEL>

Note that there is NO Message Terminator record sent after the request. The receiver is responsible for sending the Message Terminator after replying to the Request Information query.

The logical structure of the **Identification Message** response sent by the Analyzer is:

Identification Message
        Message Header Record
        Message Terminator Record

If transmission is terminated prior to the Message Terminator record sent by the Analyzer being received and acknowledged, the entire message must be retransmitted in a new session.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Send **<BEL>** character
Send Identification (Header) record	→	

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Acknowledge receipt of Identification (Header) record
Send Message Termination record	→	
	←	Acknowledge receipt of Message Termination record
	←	Send EOT to release the line

5.2 Order Communication Session

The Order communication session is initiated by the laboratory computer. This type of session is used to send information about the samples to be tested to the instrument.

The logical structure of the **Order Message** sent by the laboratory computer is:

Message Header
    Order Record 1
    Order Record 2
    .
    .
    .
    Order Record n
Message Terminator

If transmission is terminated prior to the Message Terminator record sent by the laboratory computer being received and acknowledged, the entire message may have to be transmitted for some instruments. For other instruments, the records that were acknowledged may be stored.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Send ENQ to acquire the line
Acknowledge ENQ	→	
	←	Send Header record
Acknowledge receipt of Header record	→	
	←	Send first Order record.
Acknowledge receipt of first Order record	→	
	←	Send second Order record
Acknowledge receipt of second Order record	→	
	←	Send nth Order record
Acknowledge receipt of nth Order record	→	
	←	Send Message Termination record
Acknowledge receipt of Message Termination record	→	
	←	Send EOT to release the line

5.3 Results Reporting Communication Session

The Results Reporting communication session is initiated by the Analyzer. When the Analyzer has a test result to send, it is responsible for notifying the laboratory computer system. If the laboratory computer system acknowledges the Analyzer, the Analyzer then sends the test results.

The results for a single patient are contained within a message. Each message block contains the patient and result records for a single specimen. A single specimen's patient and result records may span more than one message block. Multiple patient records <u>are never</u> sent within the same

message block, no matter how much available space remains within the block. The logical structure of the **Results Message** is:

Header
>**Patient 1**
>>**Result 1**
>>**Result 2**
>>**.**
>>**.**
>>**Result n**

Message Terminator

Header
>**Patient 2**
>>**Result 1**
>>**Result 2**
>>**.**
>>**.**
>>**Result n**

Message Terminator

Header
>**Patient n**
>>**Result 1**
>>**Result 2**
>>**.**
>>**.**
>>**Result n**

Message Terminator

If transmission is terminated prior to the Message Terminator record being received and acknowledged, the entire message must be retransmitted in a new session. That is, the patient records and all result records for that patient must be retransmitted.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
Send ENQ to acquire the line	→	
	←	Acknowledge ENQ
Send Header record	→	
	←	Acknowledge receipt of Header record
Send first Patient record	→	
	←	Acknowledge receipt of Patient record
Send first Result record for Patient	→	
	←	Acknowledge receipt of first Result record
If there are additional Result records for the Patient, send the next Result record.	→	
	←	Acknowledge receipt of each Result record.

CLINITEK 500 Analyzer		Laboratory Computer System
When all the Result records for this patient have been sent, send the Message Terminator record.	→	
	←	Acknowledge receipt of Message Terminator record.
If additional patient records need to be reported, start another message block by sending ENQ to acquire the line.	→	
Send ENQ to acquire the line	→	
	←	Acknowledge ENQ
Send Header record	→	
	←	Acknowledge receipt of Header record.
Send next Patient record	→	
	←	Acknowledge receipt of Patient record
Send first Result record for Patient	→	
	←	Acknowledge receipt of first Result record
If there are additional Result records for the Patient, send the next Result record.	→	
	←	Acknowledge receipt of each Result record.
When all the Result records for this patient have been sent, send the Message Terminator record.	→	
	←	Acknowledge receipt of Message Terminator record.
When all the patient records and corresponding result records have been sent, send EOT to release the line and end the session.	→	

It is not uncommon for data to be collected from several instruments connected to one computer through a multiplexer. Data collection using an ASTM protocol and a multiplexer can become very time consuming since the multiplexer checks for data port-by-port in a round robin fashion. When an instrument has sent an **<ENQ>** to signal that it has data to send, it also sets a timer. The instrument must then wait 15 seconds before attempting to contact the computer again. Since the port is not constantly monitored in a multiplexer setting, it is quite possible that the instrument sends the **<ENQ>** to acquire the line just prior to the multiplexer returning to that instrument's port for monitoring. The full 15 seconds will have to pass before the instrument can again send an **<ENQ>**. The CCS has added support for the **<SYN>** character to counteract the inherent time delays on a multiplexer port. If the **<SYN>** character is received by the instrument, the instrument immediately resends the **<ENQ>** and resets its timer. This allows the instrument and computer to establish a communication session and get a result record sent within the time frame the multiplexer is monitoring that particular port.

CLINITEK® 500 Implementation
of the
CLINITEK Communication Standard
for Clinical Results Reporting

1. Introduction

This document provides the CLINITEK® 500 Urine Chemistry Analyzer implementation of the CLINITEK Communication Standard, Dwg. SS000700. This document defines the message content for the information that passes between the CLINITEK7 500 Urine Chemistry Analyzer and a laboratory computer. Please refer to the CLINITEK Communication Standard for information about data codes, transmission protocol, terminology, and error recovery.

2. Low Level Protocol Support

2.1 Character Structure

The CLINITEK 500 Analyzer supports 7 data bits and even parity, 7 data bits and odd parity, or 8 data bits and no parity.

The default character structure consists of 1 start bit, 8 data bits, no parity bit, and 1 stop bit.

2.2 Speed

The data transmission rates supported are 2400, 4800, 9600, and 19200.

The default data transmission rate is 9600 baud.

3. Message Structure and Content

This part of the specification defines the message types supported and the structure of those message types and their supporting records. Each message consists of a hierarchy of records of various types.

When processing a message, the laboratory computer system may ignore any field it does not require. All fields in a record are ALWAYS transferred, and the fields are ALWAYS transferred in the positional order specified to facilitate accurate identification by the computer system. All fields in records are variable length fields.

The following types of records are supported by the CLINITEK 500 Analyzer:
Message Header Record
Request for Identification Record
Patient Record
Result Record
Message Terminator Record

3.1 Message Header Record (H)

The Message Header record marks the beginning of a message. It is ALWAYS the first record sent in a message.

Message Header Record Format

1	2	3	4	5	6	7	8
Record Type	Delimiter Definition	Message Control ID	Access Password	Sender Name	Sender Street Address	Reserved Field	Sender Telephone Number

9	10	11	12	13	14	15
Characteristics of Sender	Receiver ID	Comments	Processing ID	Version No.	Date & Time of Message	<CR>

Example of Message Header Record

H | \^& | | | BAYER^6470 ^^00.20/XP.11 | | | | | | 010 | P | 1| 19970526102030 <CR>

Field Definitions

Record Type
The Record Type is H for a Header Record.

Delimiter Definition
The five ASCII characters that immediately follow the Record Type (H) define the delimiters used for all record types. The second character in the header is the field delimiter (|), the third character in the header is the repeat delimiter (\), the fourth character is the component delimiter (^), and the fifth character is the escape delimiter (&).

Message Control ID
The Message Control ID field holds a unique number or other ID that identifies the transmission for use in network systems that have defined acknowledgment protocols that are outside the scope of ASTM Specification E1394. CCS does not use this field. Its position is represented by the field delimiter.

Access Password
This field is used for a password as mutually agreed upon by the sender and receiver. CCS does not use this field. Its position is represented by the field delimiter.

Sender Name
The Sender Name field is a component field. It defines the manufacturer, the instrument product code, the serial number, and the software version. The manufacturer name is the first component. The instrument product code is the second component. The manufacturer name and the instrument product code are required. The third component is the serial number. The serial number is an optional component. If the serial number component is not used, its position is represented by the component delimiter. The fourth component is the software version. The software version is a required component.

Sender Street Address
This field is for the sender's street address. CCS does not use this field. Its position is represented by the field delimiter.

Sender Telephone Number
This field is for the sender's telephone number. CCS does not use this field. Its position is represented by the field delimiter.

Characteristics of Sender
This field contains any characteristics of the sender such as parity, checksums, optional protocols, etc. necessary for establishing a communication link with the sender. Since this information is normally provided in the Bayer instrument's setup routine, this field will not always contain information and may be represented by the field delimiter.

Receiver ID
This field includes the name or other ID of the receiver. It is used to verify that the transmission is indeed being received by the intended party. CCS does not use this field. Its position is represented by the field delimiter.

Comments or Special Instructions
This field is a component field. Currently there is one component defined. The first component contains the language/result unit code.

Language/Result Unit Codes				
English Conventional-Normal	010		German SI-Normal	070	
English Conventional-PLUS System	011		German SI-PLUS System	071	
English SI-Normal	020		Italian-Normal	080	
English SI-PLUS System	021		Italian-PLUS System	081	
English Nordic-Normal	030		Japanese-Normal	090	
English Nordic-PLUS System	031		Japanese-PLUS System	091	
French Conventional-Normal	040		Spanish-Normal	100	
French Conventional-PLUS System	041		Spanish-PLUS System	101	
French SI-Normal	050		Chinese-Normal	110	
French SI-PLUS System	051		Chinese-PLUS System	111	
German Conventional-Normal	060		Portuguese-Normal	120	
German Conventional-PLUS System	061		Portuguese-PLUS System	121	

Processing ID
This field indicates how this message is to be processed:
- P for Production:
This software has passed all validation criteria and has been production released. The test results may be relied upon for clinical use.
- T for Training:
This software has been released for training purposes only. Test results obtained from this software are not for clinical use.
- D for Debugging:
This software has been released for debugging/testing purposes only. Test results obtained from this software are not for clinical use.
- Q for Quality Control:
  This software has been released for the purpose of obtaining quality assurance or regulatory data. Although the portions of the software that collect and process the data have been validated, the test results obtained from this software are not for clinical use.

Version Number

This value identifies the version level of the CLINITEK® Communication Standard Specification. This value is currently one (1).

Date and Time of Message Transmission
This field contains the date and time this header record was sent. The format for this field is YYYYMMDDHHMMSS.

3.2 Message Terminator Record (L)

The Message Terminator record marks the end of the message. It is ALWAYS the last record sent in a message.

Message Terminator Record Format

1	2	3	4
Record Type	Record Sequence Number	**Termination Code**	**<CR>**

Example of Message Terminator Record

L | 1 | N <CR>

or

L | 1 <CR>

Field Definitions

Record Type
The Record Type is L for a Message Terminator record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message. Since there is only one Message Terminator record per message, this field ALWAYS has a value of 1.

Termination Code
The Termination Code provides an explanation for the reason the message ended. The valid Termination Codes are:

null field or N - normal termination
T - sender aborted
R - receiver requested abort
E - unknown system error
Q - error in last request for information
I - no information available from last query
F - last request for information processed

3.3 Request Information Record (Q)

The Request Information record is used by the computer system to request that the receiver identify itself by sending its Message Header Record.

Request Information Record Format

1	2	3
Record Type	Record Sequence Number	**<CR>**

Example of Request Information Record

Q | 1   <CR>

Field Definitions

Record Type
The Record Type is Q for a Request Information Record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

3.4 Patient Record (P)

This record contains information about a sample that applies to every Result record for that sample.

Patient Record Format

1	2	3	4	5	6	7	8
Record Type	Record Sequence Number	Test Sequence Number	Date and Time	Sample ID	Tech ID	Sample Location	<CR>

1	2	3	4	5	6	8	9	10
Record Type	Record Sequence Number	Results Format	Test Mode	Test Strip ID	Transfer Status	Error Code	Auxiliary Information	<CR>

Example of Patient Record

P | 1 | 00001 | 19970526102000 | 312432216 | 34010 <CR>

P | 2 | C | P | MULTISTIX 10 SG | F | 0000 <CR>

Field Definitions

Record Type
The Record Type is P for a Patient Record.

Record Sequence Number
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Test Sequence Number
The Test Sequence Number field holds the sequence number assigned to this test strip by the instrument. The actual format of the sequence number is 5 numeric characters for patient results, 4 numeric characters with a leading 'C' for control results.

Date and Time
This field contains the date and time the test strip was read at the first readhead. The format for this field is YYYYMMDDHHMMSS. For the CLINITEK 500 Analyzer, the seconds field is always 00.

Sample ID
This field is optional. If the Sample ID option is set to OFF or if no Sample ID was entered for this test, this field will be empty. If the Tech ID option is set to ON, a field delimiter is used to mark the position of this field.

Tech ID
This field is optional. If the Tech ID option is set to OFF, this field will be empty. Since this is the last field in this record, a field delimiter is not needed to mark the position of this field if it is empty.

Results Format
This field holds the code for the output format of the results. The results format is C for Clinical results.

Test Mode
The Test Mode field defines the type of test being run. For the CLINITEK 500 Analyzer, the test mode can be P for Patient or C for Control.

Test Strip ID
The Test Strip ID field defines the type of reagent test strip used for the test. The CLINITEK 500 Analyzer supports the following reagent test strips:

MULTISTIX	N-MULTISTIX SG
MULTISTIX 10 SG	NEPHROSTIX L
MULTISTIX 9 SG	URO-HEMACOMBISTIX SG L
MULTISTIX 8 SG	UR0-LABSTIX SG
MULTISTIX SG	UR0-LABSTIX SG L
MULTISTIX SG L	

Transfer Status
The transfer status is F for First Time Transfer.

Error Code
The Error Code field always contains a value. If valid results were able to be calculated for the test strip, the Error Code field contains a value of 0000. If a problem was detected which prevents Clinical result values being reported, this field contains a code which defines the source of the problem:

	Error Code	
	Readhead 1	**Readhead 2**
Low Dark Value	0100	0001
High Dark Value	0200	0002
A-D Converter Over-range	0300	0003
Low Lamp(s) Level	0400	0004
Low Channel Output	0500	0005
Missing Strip	N/A	0006
Upside Down/Dry Strip	0700	N/A
Misaligned Strip	0800	0008
Skewed Strip	0900	0009
Reflectance > 100%	1000	0010
Auto Strip Type Error	2000	N/A

The error code field may contain a value which represents multiple errors. For example, if a low dark value was detected under readhead 1 and a skewed strip was detected when the strip reached readhead 2, the error code reported would be 0109.

Auxiliary Test Information
Not transmitted in clinical mode.

3.5 Result Record (R)

Each Result record contains the result of a single test determination. Because our urine chemistry test strips contain multiple chemistry tests, there will be one Result record for each result reported. If Color and/or Clarity are also reported, each of these physical results will also be contained in a separate record.

A result record may never appear without a preceding patient record.

Result Record Format

1	2	3	4	5	6	7
Record Type	Record Sequence Number	Test Result Status	Test Name Abbreviation	Test Number ID	Test Result Value and Result Unit of Measure	Clinical Result Level

8	9	10	11
Altered Decode Status	Result Origin	Auxiliary Test Information	<CR>

Example of Result Record for Clinical Results

R | 1 | N | PRO | 6 | 100 ^ mg/dL | 4 | 0 | A <CR>

Example of Result Record for Test Mode Results

R | 1 | N | PRO | 6 | 100 ^ mg/dL | 4 | 0 | A | 413^264^264^200^0639 <CR>

Field Definitions

Record Type
The Record Type is R for a Result Record.

Record Counter
The Record Sequence Number defines the *ith* occurrence of this record type within the message.

Test Result Status
The Test Result Status field stores code which defines whether the result is considered normal or abnormal. If the result is within the normal range for the test, this field contains an N. If the test result is outside the normal range for the test, this field contains an A.

Test Name Abbreviation
This field contains the abbreviation for the test pad or physical value. The abbreviations are language dependent.

Test Identification Number
The Test Identification Number field contains a numeric value for the test. Assigning a numeric value for each test provides a non-language dependent identifier for later data analysis.

Test	Numeric ID
Glucose(GLU)	1
Bilirubin (BIL)	2
Ketone (KET)	3
Specific Gravity (SG)	4
Occult Blood (BLO)	9
pH (pH)	5
Protein (PRO)	6
Urobilinogen (URO)	7
Nitrite (NIT)	8
Leukocytes (LEU)	10
Color	11
Clarity	12

Test Result Value ^ Result Unit of Measure
This field contains the clinical test result divided into a numerical component and a result unit of measure component. If the test result is a one word result such as POSITIVE, NEGATIVE, CLEAR, or YELLOW, that result is positioned in the Test Result Value component of the field. For one word results, no component delimiter is used since the Result Unit of Measure portion of the field is empty. For color and clarity results, no component delimiter is used.

Clinical Result Level
The Clinical Result Level field holds the level of the result with respect to the total number of reportable clinical result levels for the test. A level of 1 is always assigned to the lowest or NEGATIVE test value. For example, assume there are five result levels for a chemistry test:

1. NEGATIVE
2. TRACE
3. 30 mg/dL
4. 100 mg/dL
5. >=300 mg/dL

Since the value of 100 mg/dL is the 4th result level, the value assigned to the Clinical Result Level field would be 4.

Altered Decode Status
The Altered Decode Status field contains a 0 if altered decodes are not used. This field contains a 1 if altered decodes are used.

Result Origin
The Result Origin field contains the code which defines the source of the test result. If the result was calculated by the Analyzer, the value of this field is A. If the result was manually entered, the value of this field is M. If the result was edited, the value of this field is E. For Clinical Results, this is the last field in the record.

Auxiliary Information
The Auxiliary Information field is not used for Clinical Result records (Result records for a Patient Record with a value of 'C' in the Results Format field).

4. Communication Session Support

The CLINITEK® 500 Analyzer supports two types of communication sessions: a Request for Identification session and a Results Reporting session.

4.1 Request for Identification Communication Session

The Request for Identification communication session is initiated by the laboratory computer. Two different types of sessions are supported: a standard ASTM messaging session and a simple, single character message session.

Standard ASTM Identification Request Session

This type of session uses two types of messages: the Request Information Message sent by the laboratory computer and the Identification Message sent by the Analyzer.

The logical structure of the **Identification Request Message** sent by the laboratory computer is:

I**dentification Request Message**
    Message Header Record
    Request Information Record

The Request Information Record must be sent to the Analyzer in a separate frame from the Header Record.
Note that there is NO Message Terminator record sent after the Request Information record.
The receiver is responsible for sending the Message Terminator after replying to the Request

Information query.

The logical structure of the **Identification Message** response sent by the Analyzer is:

Identification Message
    Message Header Record
    Message Terminator Record

If transmission is terminated prior to the Message Terminator record sent by the Analyzer being received and acknowledged, the entire message must be retransmitted in a new session.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Send ENQ to acquire the line
Acknowledge ENQ	→	
	←	Send Header frame
Acknowledge Header frame	→	
	←	Send Request for Identification frame
Acknowledge receipt of Request for Identification frame	→	
Send Identification (Header) frame	→	
	←	Acknowledge Identification (Header) frame
Send Message Termination frame	→	
	←	Acknowledge Message Termination frame
	←	Send EOT to release the line

Single Character Identification Request Session

This type of session uses the **<BEL>** character to request the Identification Message be sent by the instrument.

The logical structure of the **Single Character Identification Request Session** sent by the laboratory computer is:

I**dentification Request Message**
    <BEL>

Note that there is NO Message Terminator record sent after the request. The receiver is responsible for sending the Message Terminator after replying to the Request Information query.

The logical structure of the **Identification Message** response sent by the Analyzer is:

Identification Message
    Message Header Record
    Message Terminator Record

If transmission is terminated prior to the Message Terminator record sent by the Analyzer being received and acknowledged, the entire message must be retransmitted in a new session.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Send **<BEL>** character
Send Identification (Header) frame	→	
	←	Acknowledge receipt of Identification (Header) frame
Send Message Termination frame	→	
	←	Acknowledge receipt of Message Termination frame
	←	Send EOT to release the line

The actual data exchanged for the Standard ASTM Identification Request Session looks like:

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer System
1.		
2.		**<ENQ>**
3.	**<ACK>**	
4.		**<STX>1** H|\^&|||Laboratory Computer System Name|||||| |P|1|19970526101230<CR> **<ETX>C1 C2<CR><LF>**
5.	**<ACK>**	
6.		**<STX>2** Q|1<CR> **<ETX>C1 C2<CR><LF>**
7.	**<ACK>**	
8.	**<STX>1** H|\^&|||BAYER^6740^^01.00/01.00||||||010|P|1|19970526101300**<ETX>C1 C2<CR><LF>**	
9.		**<ACK>**
10.	**<STX>1** L|1|N<CR> **<ETX>C1 C2<CR><LF>**	
11.		**<ACK>**
12.		**<EOT>**

The actual data exchanged for the Simple One Character Identification Request Session looks like:

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer System
1.		
2.		**<BEL>**
3.	**<ACK>**	
4.	**<STX>1** H|\^&|||BAYER^6740^^01.00/01.00||||||010|P|1|19970526101300**<ETB>C1 C2<CR><LF>**	
5.		**<ACK>**
6.	**<STX>2** L|1|N<CR> **<ETX>C1 C2<CR><LF>**	
7.		**<ACK>**
8.		**<EOT>**

4.2 Results Reporting Communication Session

The Results Reporting communication session is initiated by the Analyzer. When the Analyzer has a test result to send, it is responsible for notifying the laboratory computer system. If the laboratory computer system acknowledges the Analyzer, the Analyzer then sends the test results.

The logical structure of the **Results Message** is:

Header
 Patient 1
  Result 1
  Result 2
  .
  .
  Result n
Message Terminator

Header
 Patient 2
  Result 1
  Result 2
  .
  .
  Result n
Message Terminator

Header
 Patient n
  Result 1
  .
  Result n
Message Terminator

If transmission is terminated prior to the Message Terminator record being received and acknowledged, the entire message must be retransmitted in a new session. That is, the patient records and all result records for that patient must be retransmitted.

The communication session looks like:

CLINITEK 500 Analyzer		Laboratory Computer System
Send ENQ to acquire the line	→	
	←	Acknowledge ENQ
Send Header frame	→	
	←	Acknowledge receipt of Header frame
Send first Patient frame	→	
	←	Acknowledge receipt of Patient frame
Send first Result frame for Patient	→	
	←	Acknowledge receipt of first Result frame
If there are additional Result frames for the Patient, send the next Result frame.	→	

CLINITEK 500 Analyzer		Laboratory Computer System
	←	Acknowledge receipt of each Result frame.
When all the Result frames for this patient have been sent, send the Message Terminator frame.	→	
	←	Acknowledge receipt of Message Terminator frame.
If additional patient frames need to be reported, start another message block by sending ENQ to acquire the line.	→	
Send ENQ to acquire the line	→	
	←	Acknowledge ENQ
Send Header frame	→	
	←	Acknowledge receipt of Header frame.
Send next Patient frame	→	
	←	Acknowledge receipt of Patient frame
Send first Result frame for Patient	→	
	←	Acknowledge receipt of first Result frame
If there are additional Result frames for the Patient, send the next Result frame.	→	
	←	Acknowledge receipt of each Result frame.
When all the Result frames for this patient have been sent, send the Message Terminator frame.	→	
	←	Acknowledge receipt of Message Terminator frame.
When all the patient frames and corresponding result frames have been sent, send EOT to release the line and end the session.	→	

To illustrate the transfer of data from the CLINITEK 500 Analyzer to a laboratory computer system, assume the urine chemistry test type is MULTISTIX 10 SG and Color is reported, but Clarity is not reported. Assume all chemistry tests on the strip are reported. If three tests were run, the results would be printed as:

```
00001 05-26-97 10:25 AM
Tech ID: 323
ID: 312445446
  COL YELLOW
* GLU  250 mg/dL
  BIL NEGATIVE
 !KET NEGATIVE
  SG <=1.005
* BLO SMALL
  pH 6.0
  PRO NEGATIVE
  URO 1.0 E.U./dL
  NIT NEGATIVE
* LEU TRACE
```

```
00002 05-26-97 10:25 AM
Tech ID: 323
ID: 213543331
  COL YELLOW
  GLU NEGATIVE
  BIL NEGATIVE
  KET NEGATIVE
  SG <=1.005
  BLO NEGATIVE
  pH 5.5
  PRO NEGATIVE
  URO 0.2 E.U./dL
  NIT NEGATIVE
  LEU NEGATIVE

00003 05-26-97 10:25 AM
Tech ID: 323
ID: 398576435
* COL RED
  GLU  NEGATIVE
  BIL NEGATIVE
  KET NEGATIVE
  SG <=1.005
* BLO MODERATE
  pH 6.0
  PRO NEGATIVE
  URO 1.0 E.U./dL
  NIT NEGATIVE
* LEU LARGE
```

For a successful communication session, the actual data exchange looks like:

Row	CLINITEK 500 Analyzer ▶▶▶	◀◀◀ Laboratory Computer
1.		
2.	**<ENQ>**	
3.		**<ACK>**
4.	**<STX>1** H|\^&|||BAYER^6740^^01.00/01.00||||||010|P|1|19970526102500<CR> **<ETX>C1 C2<CR><LF>**	
5.		**<ACK>**
6.	**<STX>2** P|1|00001|19970526102500|312445446|323<CR> P|2|C|P|MULTISTIX 10 SG|F|0000<CR> **<ETX>C1 C2<CR><LF>**	
7.		**<ACK>**
8.	**<STX>3** R|1|N|COL|12|YELLOW|1|0|A<CR> R|2|A|GLU|1|250^mg/dL|3|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|E<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|SMALL|4|0|A<CR> **<ETB>C1 C2<CR><LF>**	
9.		**<ACK>**
10.	**<STX>4** R|7|N|pH|5|6.0|3|0|A<CR> R|8|N|PRO|6|NEGATIVE|1|0|A<CR> R|9|N|URO|7|1.0^E.U./dL|2|0|A<CR> R|10|N|NIT|8|NEGATIVE|1|0|A<CR> R|11|A|LEU|10|TRACE|2|1|0<CR> **<ETB>C1 C2<CR><LF>**	
11.		**<ACK>**
12.	**<STX>5** L|1<CR> **<ETX>C1 C2<CR><LF>**	
13.		**<ACK>**
14.	**<ENQ>**	
15.		**<ACK>**
16.	**<STX>1** H|\^&|||BAYER^6740^^01.00/01.00||||||010|P|1|19970526102600<CR> **<ETX>C1 C2<CR><LF>**	
17.		**<ACK>**
18.	**<STX>2** P|1|00002|19970526102500|213543331|323<CR> P|2|C|P|MULTISTIX 10 SG|F|0000<CR> **<ETX>C1 C2<CR><LF>**	
19.		**<ACK>**

Row	CLINITEK 500 Analyzer **ÞÞÞ**	**ÜÜÜ** Laboratory Computer
20.	**<STX>3** R|1|N|COL|12|YELLOW|1|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|E<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|N|BLO|9|NEGATIVE|1|0|A<CR> **<ETB> C1 C2<CR><LF>**	
21.		**<ACK>**
22.	**<STX>4** R|7|N|pH|5|5.5|2|0|A<CR> R|8|N|PRO|6|NEGATIVE|1|0|A<CR> R|9|N|URO|7|0.2^E.U./dL|1|0|A<CR> R|10|N|NIT|8|NEGATIVE|1|0|A<CR> R|11|N|LEU|10|NEGATIVE|1|0|A<CR> **<ETB>C1 C2<CR><LF>**	
23.		**<ACK>**
24.	**<STX>5** L|1<CR> **<ETX>C1 C2<CR><LF>**	
25.	**<ENQ>**	
26.		**<ACK>**
27.	**<STX>1** H|\^&|||BAYER^6740^^1.00/01.00||||||010|P|1|19970526102500<CR> **<ETX>C1 C2<CR><LF>**	
28.		**<ACK>**
29.	**<STX>2** P|1|00003|19970526102500|398576435|323<CR> P|2|C|P|MULTISTIX 10 SG|F|0000<CR> **<ETX>C1 C2<CR><LF>**	
30.		**<ACK>**
31.	**<STX>3** R|1|A|COL|12|RED|3|1|A<CR> R|2|N|GLU|1|NEGATIVE|1|1|A<CR> R|3|N|BIL|2|NEGATIVE|1|1|A<CR> R|4|N|KET|3|NEGATIVE|1|1|A<CR> R|5|N|SG|4|<=1.005|1|1|A<CR> R|6|A|BLO|9|MODERATE|4|1|A<CR> **<ETB> C1 C2<CR><LF>**	
32.		**<ACK>**

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer
33.	`<STX>4` R|7|N|pH|5|6.0|3|1|A<CR> R|8|N|PRO|6|NEGATIVE|1|1|A<CR> R|9|N|URO|7|1.0^E.U./dL|2|1|A<CR> R|10|N|NIT|8|NEGATIVE|1|1|A<CR> R|11|A|LEU|10|LARGE|5|1|A<CR> `<ETB>C1 C2<CR><LF>`	
34.		`<ACK>`
35.	`<STX>5` L|1|N<CR> `<ETX>C1 C2<CR><LF>`	
36.		`<ACK>`
37.	`<EOT>`	

If the laboratory computer calculates a different checksum value for a frame, it must refuse to accept that frame and the Analyzer resends the frame. A frame may be resent a maximum of six times. If the frame can still not be accepted after the sixth transfer of the frame, the Analyzer must terminate the communication session. A new session may then be initiated by the Analyzer.

To illustrate the successful retransmission of a frame, look at a retransmission of the third frame's results in our previous example. In this instance, the laboratory computer does not calculate the same checksum value as that sent by the Analyzer for the third frame (line 7). The laboratory computer refuses to accept the frame (**<NAK>**), and the Analyzer resends that frame.

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer
1.	`<ENQ>`	
2.		
3.	`<STX>1` H|\^&|||BAYER^6740^^1.00/01.00||||||010|P|1|19970526102500<CR> `<ETX>C1 C2<CR><LF>`	
4.		
5.	`<STX>2` P|1|00003|19970526102500|398576435|323<CR> P|2|C|P|MULTISTIX 10 SG|F|0000<CR> `<ETX>C1 C2<CR><LF>`	
6.		`<ACK>`
7.	`<STX>3` R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> `<ETB> C1 C2<CR><LF>`	
8.		`<NAK>`

Row	CLINITEK 500 Analyzer　　　**ÞÞÞ**	**ÜÜÜ**　Laboratory Computer
9.	**<STX>3** R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> **<ETB> C1 C2<CR><LF>**	
10.		**<ACK>**
11.	**<STX>4** R|7|N|pH|5|6.0|3|0|A<CR> R|8|N|PRO|6|NEGATIVE|1|0|A<CR> R|9|N|URO|7|1.0^E.U./dL|2|0|A<CR> R|10|N|NIT|8|NEGATIVE|1|0|A<CR> R|11|A|LEU|10|LARGE|5|0|A<CR> **<ETB>C1 C2<CR><LF>**	
12.		**<ACK>**
13.	**<STX>5** L|1|N<CR> **<ETX>C1 C2<CR><LF>**	
14.		**<ACK>**
15.	**<EOT>**	

If the third frame was not able to be successfully retransmitted after six attempts, the data exchange would end like this:

Row	CLINITEK 500 Analyzer　　　**ÞÞÞ**	**ÜÜÜ**　Laboratory Computer
1.	**<ENQ>**	
2.		
3.	**<STX>1** H|\^&|||BAYER^6740^^1.00/01.00|||||010|P|1|19970526102500<CR> **<ETX>C1 C2<CR><LF>**	
4.		
5.	**<STX>2** P|1|00003|19970526102500|398576435|323<CR> 　　　P|2|C|P|MULTISTIX 10 SG|F<CR> **<ETX>C1 C2<CR><LF>**	
6.		**<ACK>**

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer
7.	**<STX>3** R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> **<ETB> C1 C2<CR><LF>**	
8.		**<NAK>**
9.	**<STX>3** R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> **<ETB> C1 C2<CR><LF>**	
10.		**<NAK>**
11.	**<STX>3** R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> **<ETB> C1 C2<CR><LF>**	
12.		**<NAK>**
13.	**<STX>3** R|1|A|COL|12|RED|3|0|A<CR> R|2|N|GLU|1|NEGATIVE|1|0|A<CR> R|3|N|BIL|2|NEGATIVE|1|0|A<CR> R|4|N|KET|3|NEGATIVE|1|0|A<CR> R|5|N|SG|4|<=1.005|1|0|A<CR> R|6|A|BLO|9|MODERATE|5|0|A<CR> **<ETB> C1 C2<CR><LF>**	
14.		**<NAK>**

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer
15.	**\<STX\>3** R|1|A|COL|12|RED|3|0|A\<CR\> R|2|N|GLU|1|NEGATIVE|1|0|A\<CR\> R|3|N|BIL|2|NEGATIVE|1|0|A\<CR\> R|4|N|KET|3|NEGATIVE|1|0|A\<CR\> R|5|N|SG|4|<=1.005|1|0|A\<CR\> R|6|A|BLO|9|MODERATE|5|0|A\<CR\> **\<ETB\> C1 C2\<CR\>\<LF\>**	
16.		**\<NAK\>**
17.	**\<STX\>3** R|1|A|COL|12|RED|3|0|A\<CR\> R|2|N|GLU|1|NEGATIVE|1|0|A\<CR\> R|3|N|BIL|2|NEGATIVE|1|0|A\<CR\> R|4|N|KET|3|NEGATIVE|1|0|A\<CR\> R|5|N|SG|4|<=1.005|1|0|A\<CR\> R|6|A|BLO|9|MODERATE|5|0|A\<CR\> **\<ETB\> C1 C2\<CR\>\<LF\>**	
18.		**\<NAK\>**
19.	**\<EOT\>**	

When the Analyzer initiates a new session to send results, the Patient records and ALL the Result records for the 3rd patient must be sent again.

A problem can also occur on the laboratory computer side of the communication session making it impossible for the computer to continue to receive the test results from the Analyzer. The laboratory computer would notify the Analyzer that it cannot continue to receive results by responding with an <EOT> signal instead of an <ACK> signal to a successfully received data packet. If the laboratory computer asks to terminate the communication session before all the result records have been transmitted for a patient, all the information for that patient must be resent the next time results are reported. If the laboratory computer asks to end a results reporting session after the termination for a particular message has been received, the next time results are reported, the Analyzer will not have to resend that message and begin instead with the next specimen.

Again, returning to the previously illustrated communication session using three test results, assume that after the transmission of the first result, the laboratory computer is unable to continue to receive results. The data exchange looks like:

Row	CLINITEK 500 Analyzer ÞÞÞ	ÜÜÜ Laboratory Computer
1.		
2.	**\<ENQ\>**	
3.		**\<ACK\>**

Row	CLINITEK 500 Analyzer **ÞÞÞ**	**ÜÜÜ** Laboratory Computer
4.	**<STX>1** H|\\^&|||BAYER^6740^^1.00/01.00||||||010|P|1|19970526102500<CR> **<ETX>C1 C2<CR><LF>**	
5.		**<ACK>**
6.	**<STX>2** P|1|00001|19970526102502|312445446|323<CR> P|2|C|P|MULTISTIX 8|F|0000<CR> **<ETX>C1 C2<CR><LF>**	
7.		**<ACK>**
8.	**<STX>3** R|1|N|COL|12|YELLOW|1|1|A<CR> R|2|A|GLU|1|250^mg/dL|3|1|A<CR> R|3|N|BIL|2|NEGATIVE|1|1|A<CR> R|4|N|KET|3|NEGATIVE|1|1|E<CR> R|5|N|SG|4|<=1.005|1|1|A<CR> R|6|A|BLO|9|SMALL|4|1|A<CR> **<ETB>C1 C2<CR><LF>**	
9.		**<ACK>**
10.	**<STX>4** R|7|N|pH|5|6.0|3|1|A<CR> R|8|N|PRO|6|NEGATIVE|1|1|A<CR> R|9|N|URO|7|1.0^E.U./dL|2|1|A<CR> R|10|N|NIT|8|NEGATIVE|1|1|A<CR> R|11|A|LEU|10|TRACE|2|1|A<CR> **<ETB>C1 C2<CR><LF>**	
11.		**<ACK>**
12.	**<EOT>**	

The instrument must wait at least 15 seconds before attempting to take control of the line again and send additional results. When the instrument does send an **<ENQ>** and receives a reply of **<ACK>** from the laboratory computer, the instrument will send the next set of results.